Breaking the link between Poverty and Poor Health:
A Program and Evaluation Plan of *Associação Saúde Criança* (Brazil Child Health)
based in Rio de Janeiro, Brazil

By

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"Whatever you can do or dream you can, begin it. Courage has genius, power, and magic in it. Begin it now."
-Goethe

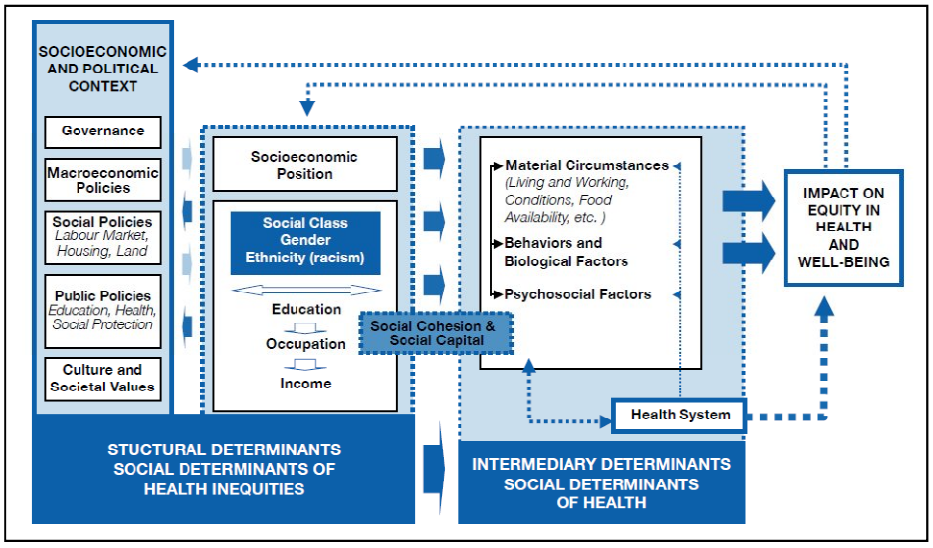
I. INTRODUCTION

It is well established that health follows a social gradient, i.e. better health with increasing socioeconomic status[1]. Not surprisingly, health outcomes and poverty continue to exist in an inverse relationship. In its most recent report, the World Bank estimates 1.29 billion people, or 22 percent of developing countries' population, lived below the extreme poverty line of $1.25 a day in 2008, down from 1.94 billion people, or 52 percent of developing countries' population, in 1981[2]. While the proportion of individuals living in extreme poverty has declined, progress has been slower at the $2 a day poverty line, around which many people in lower middle-income economies live. The number of people living below $2 a day fell from 2.59 billion in 1981 to 2.47 billion in 2008, a decrease of only 120 million. The number of people living on $1.25–$2 a day almost doubled to 1.18 billion in 2008[2]. This aggregation just above the extreme poverty line indicates the vulnerabilities faced by a great many people in the world.

Fortunately, health equity has increasingly been on the agenda of the World Health Organization (WHO) in recent years. As part of a comprehensive effort to promote greater equity in global health and in a spirit of social justice, the WHO convened a Commission on Social Determinants of Health (CSDH) to gather and review evidence on what needs to be done to reduce health inequities and provide guidance on how to reduce those avoidable, unfair and remediable differences in health outcomes between population groups, both within and among countries[3]. The CSDH submitted its report in 2008 with overarching recommendations to close the equity gap in a generation by improving daily living conditions, tackling inequitable distribution of power, money and resources, measuring and understanding the problem, and assessing the impact of action[4].

A focal point of this report included a new conceptual framework to address poverty and health outcomes. The CSDH framework shows how social, economic and political mechanisms give rise to a set of socioeconomic positions, whereby populations are stratified according to income, education, occupation, gender, race/ethnicity and other factors; these socioeconomic positions in turn shape specific determinants of health status (intermediary determinants) reflective of people's place within social hierarchies; based on their respective social status, individuals experience differences in exposure and vulnerability to health-compromising conditions. Illness can "feed back" on a given individual's social position, e.g. by compromising employment opportunities and reducing income; certain epidemic diseases can similarly "feed back" to affect the functioning of social, economic and political institutions[5]. This framework is presented in this section and also in the Appendix (Figure 1).

Figure 1: Social determinants of health (SDH) framework



Source: World Health Organization. *A Conceptual Framework for Action on the Social Determinants of Health*. Geneva, Switzerland, 2010.

To have meaning in public health, ideas and concepts need to be translated into concrete action, and interventions need to be implemented at the scale of populations. The purpose of this paper is to introduce the innovative non-governmental organization Saúde Criança based in Rio de Janeiro, Brazil, and provide a comprehensive overview of the organization's activities, context, and future directions. The first section of this paper is a systematic review to identify existing literature of current programs that adopt a "social determinants of health" framework to improve health outcomes in the developing world. This section attempts to describe lessons learned from the strengths and weaknesses of each study. The second section describes Saúde Criança from the perspective of an official program plan, providing an overview, context, theoretical basis for future implementation, and detailed goals and objectives of the NGO's current activities in Rio de Janeiro, Brazil. The third section of the paper outlines a process evaluation of Saúde Criança, including the rationale for the evaluation, the approach to the evaluation, the study design, methods, and detailed evaluation tables. The evaluation plan concludes with a discussion of potential avenues for disseminating the results of the evaluation. Lastly, the final section offers a discussion of the program as a whole, its potential for public health impact beyond Brazil's borders, and lessons for future implementation.

II. SYSTEMATIC REVIEW

Introduction

Historically, public health efforts have achieved considerable success in reducing mortality and morbidity. However few actively include means that address the social context and conditions in which people live, i.e. interventions that have a potential to contribute to greater health equity and address the root causes of illness. Even simple and effective tools, such as vaccines against childhood diseases, are unable to reach those most in need due to several social and structural factors[6].This disparity mandates a broader approach that harnesses the social determinants of health framework presented in the introduction to reduce inequities and improve health outcomes. Intersectoral action (i.e. treating education, income and sanitation as equally important components for overall well-being as health), community participation, and empowerment of populations that are most vulnerable to health threats are necessary means for a healthier, more just society[7]. These three aspects are essential components conceptual framework to improve health outcomes.

Saúde Criança is a well-established program actively leveraging this approach for over twenty years. The purpose of this literature review is to systematically identify and evaluate programs that implement a social determinants approach similar to Saúde Criança. As the focus of this paper is to guide evaluation and future implementation of the Saúde Criança model, particularly as the organization expands beyond Brazil's borders, this review was carried out with the following research question in mind: (1) *how can Saúde Criança learn from health programs combating similar realities of poverty with a social determinants approach to inform future implementation and evaluation?*

Search Strategy

In order to identify potential programs, I consulted with Mellanye Lackey, the library liaison for the UNC Gillings School of Global Public Health. It is important to note that the overall evidence base for programs addressing health through social determinants is very limited, and not surprisingly both "social determinants of health" and "global health" are not yet MeSH terms. With Mellanye's guidance, I used the search terms ((("social determinants of health" OR poverty OR "social welfare")) AND ((intervention OR assessment OR program OR evaluation)) AND "developing countries" AND ((pediatrics OR child)). I applied this search strategy in two main databases: MEDLINE and the WHO Global Health Library. I identified 196 articles in MEDLINE and 91 in the WHO Global Health Library. I then reviewed the titles and abstracts of each article in order to determine which ones met the inclusion criteria (described below). I paid particular attention to articles that focused on evaluation efforts to stay true to the focus of this paper and purposefully excluded case studies to strengthen the value of this evidence review. Inclusion criteria included:

1. The program described or evaluated addresses a health issue from a structural or intersectoral approach
2. The program takes place in the developing world
3. The article is published from 1991-2012 to correlate with the founding year of Saúde Criança
4. The article is available in English
5. The article is in full text format

After review, three articles remained which are summarized and analyzed below, and are also presented in Table 1 (Appendix).

Results

Newman, et al. (2002). The Bolivian Social Investment Program [8]

The Bolivian Social Investment Program, formally known as the Social Investment Fund (SIF), was established in 1991 as a financial institution promoting sustainable investment in the social sectors, notably health, education and sanitation. The initiative's and ultimate policy goal is to direct investments to areas that have been historically neglected by public service networks, notably poor communities. SIF funds are therefore allocated according to a municipal poverty index, but within municipalities the program is demand-driven, responding to community requests for projects at the local level. While the fund is not a formal "program" in the traditional sense, I included this study because the Fund directs its efforts from a social determinants framework. It finances programs that provide infrastructure in not only health, but also water and education in order to improve a community's overall well-being.

The study[8], carried out jointly by the World Bank and SIF, began in 1991. The study features baseline (1993) and follow-up (1997) survey data that combine to allow a before-and-after impact assessment. It includes separate evaluations of education, health and water projects and is unique in that it applies a range of evaluation techniques and examines the benefits and drawbacks of these alternative methodologies. The overall study includes separate evaluations of education, health and water projects that assess the effectiveness of the program's targeting to the poor. It also assesses the impact of its social service investments on desired community outcomes such as improved school enrolment rates, health conditions and water availability. The evaluation is also innovative in that it applies two alternative evaluation methodologies, randomization and matched comparison, to the analysis of education projects and contrasts the results obtained according to each method. This is an important contribution because

randomization (random selection of program beneficiaries within an eligible group) is widely viewed as the more statistically robust method, and yet matched comparison (using a non-random process to select a control group that most closely "matches" the characteristics of program beneficiaries) is more widely used in practice.

The 1993 baseline and 1997 follow-up surveys were applied to both the institutions that received SIF funding and the households and communities that benefit from the investments. Similar data were also collected from comparison (control group) institutions and households. The household survey gathered data on a range of characteristics, including consumption, access to basic services, and each household member's health and education status. There were separate samples for health projects (4,155 households, 190 health centers), education projects (1,894 households, 156 schools), water projects (1,071 households, 18 water projects) and latrine projects (231 households, 15 projects).

To analyze how well SIF investments were actually targeted to the poor, the study used the baseline (pre-SIF investment) data and information on where SIF investments were later placed to calculate the probability that individuals would be SIF beneficiaries conditional on their income level. The study then combined the baseline and follow-up survey data to estimate the average impact of SIF in those communities that received a SIF investment, using regression analysis. In addition to average overall impact, it explored whether the characteristics of communities, schools, or health centers associated with significantly greater than average impacts could be identified.

In education, where SIF investments were randomly assigned among a larger pool of equally eligible communities, the study applied the "ideal" randomized experiment design. In health and sanitation projects, where projects were not assigned randomly, the study used the

"instrumental variable" method to compensate for the lack of a direct counterfactual. Instrumental variables as defined in the study are correlated with the intervention but do not have a direct correlation with the outcome.

SIF-financed education projects either repaired existing schools or constructed new ones and usually also provided new desks, blackboards, and playgrounds. The study showed that these SIF investments in education resulted in a clear improvement in infrastructure and equipment, i.e. the condition of classrooms and classroom space per student. However education projects had little impact on school dropout rates, but school achievement test scores among sixth graders were significantly higher in SIF schools. In health, SIF investments provided health centers with medicines, furniture and medical equipment; a motorcycle to allow health personnel to conduct more home visits; and a radio to call for ambulances and keep in contact with other health centers. They also provided solar panels in areas without electricity and made drinking water available. These efforts raised health service utilization rates and reduced under-age-five mortality. SIF water projects involved small-scale potable water systems whose design varied depending upon the geographical location. These investments were associated with little improvement in water quality but did improve water access and quantity and also reduced mortality rates.

A comparison of the randomized versus matched-comparison results in education showed that the matched-comparison approach yielded less comparable treatment and comparison groups and therefore less robust results in discerning program impact. For example, evidence of improvements in school infrastructure (which one would expect to be present in SIF schools) is picked up in the randomized evaluation design but not in the matched-comparison design. Finally, the results showed that SIF investments were generally not well targeted to the poor.

Health and sanitation projects benefited households that were relatively better off in terms of per capita income, and there was no relationship between per capita income and SIF education benefits.

The results on targeting reveal an inherent conflict between the goal of targeting the poor and the demand-driven nature of SIF. It appears that better off, more organized communities, rather than the poorest, are those most likely to obtain SIF investments. This is an important reflection for Saúde Criança in terms of best practices for targeting the most appropriate communities in order to yield the greatest impact.

Rivera, et al. (2004). Progresa Program [9]

Progresa is a large-scale incentive-based welfare program created by the Mexican federal government. The program started in 1997 in rural areas, expanded to semi-urban areas in 2001, and lastly to urban areas in 2002. As cited in the article, the program's coverage is comprehensive: 4.5 million low-income families in 2004 (about 20% of all families in Mexico) across urban and rural areas. The program's principal aim is to develop human capital in low-income households. Similar to the Social Investment Fund, the creators believe that investments in nutrition, health, and education in young children who live in low-income environments will improve their chances of accessing higher education, better jobs, and in turn a better quality of life in adulthood. Investment in these 3 basic needs is considered central to breaking the intergenerational continuation of poverty, a goal shared by Saúde Criança.

Families enrolled in Progresa receive 2 types of cash transfers every 2 months: a universal cash amount for all families and a specific cash transfer associated with school attendance of their school-aged children enrolled in third-grade primary school to third-grade

secondary school. In order to receive these cash transfers, however, families must prove compliance with specific health care appointments in health centers for all family members, including immunizations, well baby care and growth monitoring of children, prenatal and postnatal care and education for women, check-up visits for other family members, and a mandatory session on nutrition and health education. This system of built-in accountability on behalf of families receiving benefits is an important component of social determinants implementation. As cited by the study authors, only about 1% of households were denied the cash transfers for noncompliance during the evaluation period, suggesting high-rates of compliance due to a well-designed incentive.

The authors of this study focused specifically on the short-term impact of Progresa on nutritional outcomes, measured by height increments and anemia rates via blood hemoglobin levels in participating children[9]. They also included an intermediate outcome of *papilla* intake, a micronutrient fortified food provided by Progresa to participating families along with cash transfers. The study was conducted in 6 states in the central region of the country (Guerrero, Hidalgo, Puebla, Queretaro, San Luis Potosı, and Veracruz), representing the largest area in which the program operated. With a randomized effectiveness study design, 506 communities were randomly selected to participate, with 320 assigned to begin receiving Progresa benefits immediately and 186 scheduled to begin receiving benefits two years from the start date, therefore acting as controls for 2 years. However the enrollment of the 186 communities occurred one year earlier than planned and led to a high number of crossovers. Children participants were thus followed and monitored for two consecutive years, from 1998-2000.

The researchers employed several useful methods of data collection tailored to the context of their subjects, which is particularly relevant to this review as context-sensitive data is

imperative for accurate evaluation results. These methods included corroborating verbal information with official documents (i.e. vaccination cards or birth certificates) and collecting comprehensive socioeconomic information in each household, including household characteristics (construction materials used for floors, walls, and ceilings), possession of household goods (radio, television, VCR, telephone, refrigerator laundry machine, and hot water heater), and household services (water and sanitation facilities and type of fuel used for cooking). Researchers then combined data to generate a composite socioeconomic score for statistical analysis.

The study produced impressive results: Age- and length-adjusted height was greater by 1.1 cm (26.4 cm in the intervention group vs 25.3 cm in the crossover intervention group) among infants younger than 6 months at baseline and who lived in the poorest households. After 1 year, mean hemoglobin values were higher in the intervention group (11.12 g/dL; 95% CI, 10.9-11.3 g/dL) than in the crossover intervention group (10.75 g/dL; 95% CI, 10.5-11.0 g/dL) who had not yet received the benefits of the intervention (p=.01). There were no differences in hemoglobin levels between the 2 groups at year 2 after both groups were receiving the intervention. The age-adjusted rate of anemia (hemoglobin level 11 g/dL) in 1999 was higher in the crossover intervention group than in the intervention group (54.9% vs 44.3%; p=.03), whereas in 2000 the difference was not significant (23.0% vs 25.8%, respectively; p=.40).

There are two significant weaknesses to the study: the risk of selection bias due to loss of follow-up and the number of crossovers from control to intervention arm due to political pressure to accelerate the program in Mexico. In turn, the results may underestimate the real effects of Progresa interventions because the group that was originally allocated to be the control was included in the Progresa program 1 year earlier than planned, however it would be difficult to

calculate this hypothetical magnitude of difference. The study provides an example of not only direct health benefits from a social determinants framework, but also an important model of the impact a social determinants intervention can have on a large scale such as a federal program.

Victora, et al. (2006). The Integrated Management of Childhood Illness [10]

The Integrated Management of Childhood Illness (IMCI) program was designed by WHO and UNICEF to reduce infant mortality and the incidence and seriousness of illnesses that affect children under five, as well as improve their growth and development. IMCI was proposed as a strategy to unify the vertical child health programs that were prevalent at that time, such as the Control of Diarrheal Diseases or Acute Respiratory Infections programs. IMCI has three, albeit ambitious, main components: improving the performance of health workers in first-level facilities through a training course addressing leading causes of infant and child mortality; ensuring health systems support for child health (including drug and vaccine supply, supervision and health information systems); and the strengthening of family practices needed to prevent disease, to stimulate appropriate utilization of health services, and to improve home care for sick children. The IMCI objectives were designed to address major causes of child mortality including pneumonia, diarrhea, malaria, measles and malnutrition in countries with mortality rates in children younger than 5 years (U5MRs) of 40 per 1000 live births or greater. This program adopts more of health systems approach to improving child health rather than a specific community based intervention, however their perspective and respective objectives align within a social determinants framework.

The authors of this study looked at the implementation of IMCI in three countries: Brazil, Peru, and Tanzania[10]. The objective was to assess whether the strategy was implemented in the

areas with greatest child health needs. The study was carried out through interviews with key stakeholders at the national and district levels, as well as an ecological study of factors associated with health worker training in IMCI. The baseline mortality rates in children under five years old before IMCI implementation were assessed. Also included were district characteristics (population, distance from the capital or main city, urbanization rate), environmental variables (water supply), and socioeconomic indicators (literacy, income and Gross Domestic Product). Similar to the Progresa study, the authors included context-specific data points for analysis. The district Human Development Index, which combines data on GDP per capita, education (weighted average of adult literacy rate and gross school enrollment ratio) and life expectancy at birth was calculated.

The researchers found that in Brazil, IMCI was less likely to be implemented in municipalities with low scores on the Human Development Index, low per capita income, small populations, and located further away from the state's capital. Indicators of literacy, urbanization, water supply and baseline under five mortality rate (U5MR) were not associated with IMCI implementation. In Peru, no significant correlations were found between coverage of training of health workers in IMCI and any of the indicators studied. Though correlations were weak, IMCI coverage tended to be lower in departments with higher values of the Human Development Index, larger populations and poorer water supply.

In Tanzania, the only significant correlation was the earlier introduction of IMCI in districts that were close to Dar es Salaam. None of the other correlations, including the baseline U5MR, were statistically significant. Of note, even though the WHO recommended clear criteria for selecting districts for early implementation, these did not include equity considerations (e.g. mortality levels). This incentivized the initial selection of districts that were close to the national

capital or main city, with a strong experience in previous vertical child health programs, managed by motivated teams and with sufficient funding available and IMCI tended to be adopted by other districts with similar characteristics. However, as the authors highlight "these characteristics are likely to be found in districts where the U5MRs are lower than the national average" [10]. This raises an important disconnect between top-down strategies and ground-level realities; there was a substantial time lag between the development of new concept and guidelines and their application at country level and below.

The authors acknowledge an important limitation to this study that detailed information on IMCI implementation, particularly on coverage of training for health workers, was very difficult to obtain. Also, another drawback was that, except for in Brazil, the number of study units available for analyses was limited, resulting in relatively low statistical power for detecting significant associations. Also, several likely determinants of implementation were hard to measure objectively. For example, key informants in all countries mentioned that motivation of the district health team was a major determinant of IMCI uptake. This important variable can be difficult to measure in large-scale studies without proper resources in place for evaluation.

In an ideal world, IMCI would be strongly implemented in districts with high U5MRs and lower standards of living, and among these, priority would be given to districts with a large population of children younger than five years old. The researchers are not shy to admit that this was not the case in any of the three countries studied. They urge that WHO officials should work together with countries to guide selection of the districts in which programs and strategies are deployed, to ensure that high-risk geographical areas are not left behind. Admittedly, this is easier said than done, but unless pro-active efforts are made to implement and evaluate

interventions where they are most needed, inequalities in child health may widen as a result of new programs.

Discussion

The articles reviewed here [8,9,10] provide a picture of existing efforts that aim to improve well-being from a social determinants approach. Each of the programs described measured aspects of child health and/or mortality as outcomes of targeted interventions or strategies for low-income communities in developing world contexts. Although more programs undoubtedly exist, evidence-based approaches addressing their impact and evaluation are still missing in the literature. Many studies "explain" or "describe" why an integrated approach could improve health outcomes, yet few provide complete examples of *how.* This review attempts to fill that gap and more importantly, offer lessons for future programming and evaluation as Saúde Criança continues to grow.

With regards to effective evaluation, both author groups of the Bolivian Social Investment Fund and Mexico's Progresa program portray that the randomized research design, in which a control group is selected at random from among potential program beneficiaries, is far more effective at detecting program impact than the matched comparison method of generating a control group. Randomization must be built into program design from the outset in determining the process through which program beneficiaries will be selected, and random selection is not always feasible. However, when program funds are insufficient to cover all beneficiaries, a commonly affronted problem in NGO field, an argument can be made for random selection from among a larger pool of qualified beneficiaries. This lesson comes at a timely moment for Saúde Criança for two reasons: 1) it reinforces their partnership with a group of researchers conducting

an ongoing randomized effectiveness study of long term impact for their model in Brazil (to be completed in September 2012); and 2) it is an important element to build into future implementation projects as the model expands outside of Brazil.

Also evident from this review is that evaluations can be extremely complex and time consuming. The Bolivia evaluation was carried out over the course of seven years in an attempt to rigorously capture project impact, and achieved important results in this regard. However, the evaluation was difficult to manage over this length of time and with the range of different actors involved (government agencies and financing institutions). A potential alternative for management and implementation of an evaluation effort can be streamlined by incorporating these processes into the normal course of local ministerial activities from the beginning. Further, extensive evaluation efforts may be best limited to only a few programs – for example, large programs in which there is extensive uncertainty regarding results – in which payoffs of the evaluation effort are likely to be greatest.

With regards to future program implementation, the Progresa program evaluation offers two key lessons of value to Saúde Criança: 1) shared accountability between program participants and program stakeholders is essential to program success; and 2) the inclusion of intermediate outcomes in evaluation efforts. As currently implemented in Brazil, Saúde Criança does maintain a high standard of accountability with their participants, i.e. they do not consider their efforts as "charity work" and in order to receive benefits participants must attend monthly sessions to keep a check on their progress. This element must cross country borders as the program expands outside of Brazil, not only for program success, but also for methodology integrity. The same applies for the inclusion of intermediate outcomes which Saúde Criança

currently does not measure. Possible intermediate outcomes could include: child nutritional intake or sense of self-capacity from participants while receiving benefits.

Actions on the social determinants of health must involve sectors other than health, must involve meaningful partnerships both horizontally (between program participants and stakeholders) and vertically (between international foundations and on-the-ground realities), and must focus on the whole spectrum of the population, taking account of the needs of different groups. This must be based on accurate descriptions of the social structure and must recognize the dynamic nature of that social structure. To date, there is no literature describing programs or program evaluations that aim to improve health outcomes by addressing *all* five domains central to Saúde Criança's methodology: health, housing, education, citizenship, and income generation. The articles included in this review exemplify efforts in the developing world that include several of those same components. While it is encouraging to see the impact they achieve, the evidence-base for a social determinants framework approach used in interventions remains limited. Nonetheless, incorporating lessons from the programs described here will hopefully contribute to future implementation and evaluation of Saúde Criança as the model expands.

III. PROGRAM PLAN

Overview

Grounded in principles presented in the social determinants of health conceptual framework, Associacao Saúde Criança is a program that tackles the social context and conditions in which low-income families live in Rio de Janeiro, Brazil, in order to improve health outcomes and empower communities. The ultimate aim of Saúde Criança is to reduce pediatric hospitalizations in low-resource areas by empowering families and providing tools for self-sustainability. This section describes Saúde Criança's inception, contextual factors and program theory relevant to program development, and lastly the goals, objectives, and implementation of the program itself.

Millions of citizens in Rio live in urban slums (*favelas* in Portuguese) that lack decent housing, clean water, or proper sanitation. Rocinha, a massive hillside expanse of cinderblock, wood, and tin, is one of several and the largest favela in Latin America, juxtaposed directly against the wealthy beachside enclaves of Ipanema and Leblon. Children are stunted as a result of malnutrition, and often admitted to the hospital for both infectious (e.g. preventable) etiologies and complex chronic conditions. In the late 1980s and early 1990s while treating patients at the public Hospital da Lagoa in Rio de Janeiro, pediatrician Dr. Vera Codeiro encountered the by-products of families living in the slums: children with pneumonia, tuberculosis, rheumatic fever, anemia, birth defects, and other ailments. Many children suffered from leptospirosis, a disease caused by bathing in or drinking water contaminated with rat urine, with symptoms of fever, jaundice, vomiting, and diarrhea[11].

Most concerning to Cordeiro, however, was a then accepted pattern of admission → treatment → discharge → readmission for the same condition. It became evident to Cordeiro that

investing any resources from a government-run hospital equipped with the best medical equipment and doctors was in effect useless when the larger socioeconomic context at hand was in fact the root cause of illness. Cordeiro needed others to acknowledge that childhood illnesses among the poor occur within a larger socioeconomic context in which the conditions of poverty instigate and perpetuate the symptoms of disease. Thus, is 1991, with the initial financial support of fifty colleagues totaling $100 USD in incorporation fees, she created Associacao Saúde Criança, an organization that would begin where hospital care ended[11]. Cordeiro had witnessed the multidimensional nature of poverty and understood how one child's disease affected an entire family's well-being. Thus, in a bottom-up approach, she developed a multidimensional strategy known as the Family Action Plan addressing five areas for low income families with children at risk for multiple hospitalizations: health, education, housing, income generation, and citizenship. Today, Saúde Criança works in a holistic and integrated manner, refusing to accept poverty as a reason for any child's death.

Program Context

In the last decade, Brazil as a country has experienced unprecedented economic and technological growth, particularly in the large cities of Sao Paolo and Rio de Janeiro. A testament to this growth, Brazil was selected to host the 2012 United Nations Sustainable Development Conference (Rio+20), the 2014 World Cup, and the 2016 Summer Olympic Games. However, despite a fruitful economy and growing international recognition, these cities continue to struggle in overcoming persistent problems of poverty and a low quality of government services[12]. Recognition of the inequities in health status associated with poverty, inadequate housing, lack of employment opportunities, racism, and powerlessness, has led to

calls for a renewed focus on an ecological approach in health programming that recognizes that individuals are embedded within social, political, and economic systems that shape behavior and access to resources necessary to maintain health[13]. This reality is not a new phenomenon in Rio de Janeiro Brazil, where upwards of 2 million of the city's population of 6 million live in slums[14]. While non-governmental organizations such as Saúde Criança are fighting to change this reality by empowering families, there remain context aspects that are important to consider for ongoing and future program planning.

Funding*:* A foreseeable problem common to the non-profit and development sector is a lack of funds available to finance various projects. Currently, the majority of funds to maintain Saúde Criança derive from international, corporate, and individual donations. To ensure the future sustainability of the organization, Saúde Criança has created a permanent trust fund, headed by Arminio Fraga, Brazilian economist and former president of the Central Bank of Brazil. The establishment of such an endowment is a first for any Brazilian NGO. To promote donations to the fund, Saúde Criança is exploring other forms of media and e-commerce development, beginning with a major logo-rebranding campaign organized pro-bono by the international advertising agency DM9 to increase the organization's visibility through several media avenues.

Political Environment: Another major obstacle is complications within the bureaucracy of Brazil. Saúde Criança aims ultimately to influence public policy, yet the unfortunate reality amongst local, state, and national politics is that bureaucracy is slow and internal contentions exist between departments that obstruct the development of programs. One of the major motivations for the upcoming marketing campaign is to garner greater public awareness and support for the organization. Because Saúde Criança already maintains friendly relations with

influential people within Rio such as Armínio Fraga, and internationally such as Graca Machel (Mozambique politician, humanitarian, and advocate of women's and children's rights) and Mohammed Yunus (Bangladeshi economist and Noble Peace Prize winner), more visibility will give the organization greater political clout and the ability to effect influential change.

Since its foundation in 1991, Saúde Criança has transformed itself into a pioneer in the social development sector and to date has established ten other chapters throughout Brazil. The organization has most recently launched a chapter in Sao Paolo, the largest city in Brazil. In addition, the municipality of Belo Horizonte in Minas Gerais has officially adopted Saúde Criança's methodology (the Family Action Plan) into its new health policy, "Família Cidada: Cidade Solidaria." Saúde Criança is currently working with the municipalities of Rio de Janeiro, R.J. and Florianopolis, S.C., on similar pilot programs that will elevate their methodology to a policy implementation level. Mobilizing local and state political leaders behind Saúde Criança as a public health intervention increases the community's ability to see the program as an extension of the political environment, thereby bolstering faith in government while raising awareness and providing support for the increasing need of a holistic health intervention to break the link between poverty and poor health in Rio, and potentially in settings outside of Brazil.

Besides Saúde Criança's official partnership with the municipality of Belo Horizonte and with pilot programs in Rio de Janeiro and Florianópolis, it also supports and advises 23 other NGOs that have replicated its methodology. Both of these activities help spread and attest to the strength of its work. Moreover, Saúde Criança collaborates closely with the businesses with which it is partnered. For instance, it worked intimately with McKinsey to develop its data management system and with international agency DM9 to organize its advertising campaign. These efforts and strong partnerships have significantly strengthened the organization.

Future Partnerships and Public Policy: CEDAPS (Centro de Promacao da Saude), or as they go in English, the Network of Healthy Communities of Rio de Janeiro, is a Brazilian foundation created in 2004 that advocates for equity, health promotion, and community development in the context of increasing numbers of slums in Rio. They are supported by the Dreyfus Health Foundation, the Ministry of Health, the Municipal Health Secretariat, PAHO, Ford Foundation, and universities[15], therefore represent several points of view and a diverse range of potential incentive to support interventions that empower communities within Rio. As an organization, they state:

> "By providing people with more opportunities to develop their skills, talents, and potentials, offering them more chances of participation and interaction with the civil society and the state, social capital will increase and residents will expand their ability to transform the economic, social, and cultural structure of their communities."

In addition to being scarce, public services (particularly in health and education) to low-income communities are almost always based on vertical programs, implemented without taking into account local needs, and use directive processes that "teach" participants what their problems are and the best way to solve them[16]. Residents are seen as simple recipients of programs, have few opportunities to participate in public policies, and to contribute to solve their own problems. Thus, many talents, skills, and especially, much of the available resources are wasted. Without the involvement of the community, the effectiveness of social interventions is reduced. The lack of openness of public policies to community involvement also results in reduced ownership and sustainability of social initiatives. This is a potential realm of program planning for Saúde Criança.

It is thus crucial to increase opportunities to social actors (community members and professionals) to participate in the problem solving of health related issues and in development

programs. In this context, networking of community groups can increase their political strength and become an important strategy to develop the autonomy and build the capacity of low-income communities to search for solutions for their development, to participate in the decisions and programs that affect them, and to enable them to obtain more resources and programs from the state.

National Health System: When executing an intervention targeting population health outcomes it is important to consider the structures and policies in place with regards to health services. The National Health Policy of Brazil has been developed taking into account the 1988 Federal Constitution, which established health as a right for all citizens and a duty of the State[17]. In order to translate this basic right into practice, the Brazilian Unified Health System (*Sistema Unico de Saude* or SUS) was created, based on the principles of universal and egalitarian access to comprehensive care, to ensure promotion, protection and recovery of health, integrated into a regionalized and hierarchical network of services under the responsibility of the three levels of government (Federal, State and Municipal)[18]. The private healthcare sector contributes to and supplements this effort. The purpose of the principle network of public institutions is to provide, finance and manage health services; the SUS provides complete coverage for 75% of the Brazilian population. The remaining 25% of the population – covered by the Supplementary System – also has the right to access services provided by the SUS. In addition, the SUS is responsible for the provision of collective services such as sanitation, disease control and regulation of the sector. Services of the SUS are provided through federal, state and municipal public networks, including private or philanthropic entities contracted by the system. The Supplementary System consists of private companies, units and professionals, who provide services and/or health care to their clients. The SUS is directed at the Federal level by the

Minister of Health, at the State and Municipal level by the respective Secretaries of Health. To facilitate the negotiation and agreement of policies and programs, the SUS has associate agencies: the National, State and Municipal Health Councils. Different spheres of the government, besides representatives from segments of the health sector and civil society participate in these councils[18].

In Rio de Janeiro specifically, the main program providing basic care to the population is the Family Health Program (*Plano de Saude Familiar* or PSF), covering 73 million people in 2005 (40% of the population) in 4,837 cities through the support of 22,683 multi-professional teams[19]. Since 2002, the Ministry of Health, in cooperation with the Pan-American Health Organization and the World Health Organization, has been working towards the development and strengthening of the PSF Teams[20]. SUS medical services are classified into basic health care (promotion, prevention, basic specialties and disease control), specialized medium-complexity health care, and high- complexity health care. In 2003, the system reported 2.4 medical consultations per capita/year in urban areas, 1.8 in rural areas[20]. Significant disparities in access to benefits continue to exist from region to region, particularly in the urban slums of Rio de Janeiro. Given these disparities and the complex nature of social health services in Rio de Janeiro, helping families navigate their rights to health care and ensuring proper delivery is an important component of Saúde Criança and the Family Action Plan Model.

Program Theory

Program theories have great utility in designing public health interventions. They provide a framework to explain how a specific program or intervention will address an identified health problem[21]. Currently Saúde Criança is a community level initiative. Its impact lies in reducing a population's health burden (i.e. pediatric re-hospitalizations of low-income families in Rio de

Janeiro, Brazil) by addressing injustices and disparities within a family's socio-environmental context. After twenty years, their powerful impact has potential to create national policy change and development for Brazil, and potentially beyond. Their approach necessitates an ecological perspective. As stated in the Theory at a Glance Guide, an ecological perspective "emphasizes the interaction between, and interdependence of, factors within and across all levels of a health problem"[22]. The ecological perspective recognizes multiple avenues of "change" to lead to an improved health outcome, which I believe is a core concept to the ongoing success of Saúde Criança – health is multi-faceted, and creating well-being (as the WHO defines) requires efforts outside hospital or clinic walls. The Ecological perspective I feel also aligns well with the literature supporting (and in some lights, mandating) a Social Determinants of Health Framework to tackle health inequities, particularly in developing world contexts. The Commission has raised awareness of similar programs in Latin America that will inform future program development in Brazil, and beyond.

At the interpersonal level, I will apply Social Learning Theory, which assumes that people are influenced by and influence their social environments, to better understand and replicate the organizational successes of Saúde Criança. As the goal of my program and evaluation paper will focus on how to translate a model to another context or how to best inform future program development, it will be important for me to understand the organizational aspects of the NGO which lead to its success – leadership, team dynamics, shared responsibility, interpersonal interactions, etc. The volunteers and staff members of Saúde Criança who interact daily with program participants foster an environment of support, accountability, and empowerment – all key characteristics of the social environment and culture of the program.

Lastly, but perhaps most relevant, I intend to contextualize this program plan with the key attributes of Diffusion of Innovations theory[23]. Diffusion expands the number of people who are exposed to and reached by successful interventions, strengthening their public health impact[22]. This concept is the focus of my program planning and evaluation paper. I am most interested in the dissemination of the Saúde Criança method (the Family Action Plan) to contexts/settings outside of Brazil. I will treat the methodology itself as the innovation: can this methodology translate? How can lessons learned by the leaders in Brazil inform future program development? What are the key elements of the program that are essential to its success (e.g. reducing preventable pediatric hospitalizations)? How do you account for local context? I plan to guide my program planning and future fieldwork by the questions presented in the Diffusion of Innovation Theory regarding relative advantage, compatibility, complexity, trialability, and observability[23]. These respective aspects will be further addressed in the evaluation objectives of this paper.

Goals and Objectives

The overall goals of Associacao Saúde Criança are as follows:

1. To end the vicious cycle of poverty → hospital admission → discharge → poverty → re-hospitalization for children of families living below the poverty line in Rio de Janeiro, Brazil
2. To transform the lives of families trapped in poverty by promoting self-sustainability and biopsychosocial development
3. To disseminate the Family Action Plan methodology in similar contexts throughout the world that face a high disease burden due to poverty

The objectives of the program are delineated by each component of the Family Action Plan. The FAP is the core of the Saúde Criança program and is essential to create long-lasting social

impact. Each family's FAP is created by a Saúde Criança staff member after the completion of the initial evaluation and upon the first return of the family and the responsible party for the assisted child. The goals, commitments, responsibilities, and action steps are customized to the needs of each family, and are monitored and evaluated on a monthly basis (see Appendix A for detailed steps in creating a Family Action Plan). The respective short and long-term objectives based on the FAP per household are as follows:

Short Term (1-3 years):

By the end of one year of participation:

- All children ages 0-10 up to date on vaccinations
- All children 0-10 enrolled in a primary or secondary school
- All household adults consulted for enrollment in vocational training courses
- All household adults completed psychosocial assessment by staff psychologist

By the end of three years of participation:

- Adequate nutrition status of all children
- Improved housing conditions so that each household has a home meeting basic living requirements including: running water, treated sewage, painted walls, roof without leakages, and a bathroom with flush toilet, sink, and shower.
- All household members up to date with the citizenship documents in order to claim governmental welfare benefits
- Increased sense of agency and self-esteem for head(s) of household

Long Term (3-5 years):

- By the end of five years of participation: All children enrolled or graduated from secondary schools
- Each family is self-sustained and no longer requires assistance from Saúde Criança
- Increased awareness and importance to education and psychological support within families
- Families will make healthier lifestyle choices

Logic Model

See Appendix B for the complete Logic Model.

Program Implementation

Saúde Criança is an innovative program that addresses health inequities by addressing a family or household's greater social conditions. To have meaning when addressing social determinants in public health, ideas and concepts need to be translated into concrete action, and interventions need to be implemented at the scale of populations. For Saúde Criança, this action is embodied in the Family Action Plan. The Plan's detailed steps are the crux of the activities and resources needed for each individual component (see Appendix A). In contrast to the majority of social programs that see their "beneficiaries" as passive receivers of benefits, Saúde Criança considers the families admitted to the program as *partners* in reaching the goals defined in the FAP. Therefore, the responsibilities for achieving activities outlines on the FAP are not restricted to Saúde Criança, both rather shared with the families who are constantly reminded of these commitments and encouraged to keep them. This approach will continue to contribute to successful program implementation as prospective families, often accustomed to adversity and loss, become engaged as co-participants on a trajectory of success and gains. While difficult to measure, this partnership may in fact increase self-esteem and efficacy of household leaders as outlined in the program objectives, which in turn contributes to improved health outcomes. The activities and strategies to achieve this program's goals and objectives are outlined in the Family Action Plan (Appendix A).

IV. EVALUATION PLAN

Rationale for the Evaluation

Saúde Criança should be evaluated for several reasons. Primary reasons focus on how the program is reaching its evident impact (i.e. reducing rates of pediatric hospitalizations in areas with high rates of poverty such as Rio de Janeiro, Brazil) and how the current program implementation can be improved. These evaluation objectives fall within the realm of an implementation or process evaluation. Secondary reasons focus on impact and dissemination, taking lessons from the primary objectives to inform future efforts to replicate the program in settings outside of Brazil. Both efforts (and their respective objectives) I believe warrant the use of an external evaluator in slightly different capacities. An advantage of external evaluators not funded by the program itself is that they maintain a level of objectivity that allows them to act as advocates for the program[25].

However, it is important that the evaluator balances distance with support for the program. A process evaluation will require a more participatory and interactive approach with program staff and stakeholders, as the evaluation will focus on activities within the program itself and will benefit greatly from an "insider" perspective. This may involve recruiting an internal evaluator to help or work alongside an external evaluator to ensure communication of findings, understand greater political and/or cultural influence on behaviors, etc. A summative evaluation which focuses on program replication would greatly benefit from a team of external evaluators to track population impact over a period of time. Saúde Criança has already partnered with a team of research evaluators from the Public Policy Institute at Georgetown University who are completing an outcomes evaluation with data from 2005-2007. Therefore, my main role with Saúde Criança will be as an external evaluator for the process evaluation.

Approach to the Evaluation

Patton describes four main features of a successful and useful evaluation: utility, feasibility, propriety, and accuracy[26]. These features will guide my evaluation plan. As the mini-systematic literature review revealed, there is little data published on the effectiveness of programs that improve health outcomes by addressing social determinants of health. While there is a plethora of literature justifying the need for such programs, how to execute and subsequently evaluate these efforts is missing in the literature outside of selected WHO and CDC resources. Therefore, systematically evaluating this program could not only benefit Saúde Criança, but also a greater audience of program planners. Additionally, Saúde Criança has built partnerships in order to launch pilot programs outside of Brazil. Evaluation is imperative for the establishment and success of future dissemination efforts. The results of an implementation and summative evaluation combined would be invaluable to this program.

Key skills of an effective evaluator include: an "ability to listen, negotiate, bring together multiple perspectives, and assist in developing an evaluation design that will lead to the most useful and important information and final products"; is flexible and able to problem solve; and skilled in evaluation research and methods[25]. Particular to Saúde Criança, sensitivity to the bureaucratic and political context of Brazil is essential. Communication skills and an ability to interact with a range of individuals, from low-income program participants to affluent sponsors is also a necessary skill. Qualitative research methods will be of great use in identifying strengths and weaknesses of the program activities themselves, and how the specific activities outlined in the Family Action Plan – the core of the program's methodology – lead to better health outcomes. Therefore, the evaluator should be grounded in qualitative research methodology and

have experience with qualitative data analysis. A qualitative lens will allow the evaluator to engage with program stakeholders while also maintaining objectivity.

Stakeholders: There are multiple stakeholders involved in the current success of Saúde Criança therefore their respective perspectives are imperative for a useful evaluation. These stakeholders include: Founder and CEO Dr. Vera Cordeiro; current COO Cristiana Velloso; former COO Martha Scodro; director of dissemination Teresa Sanchol; Site Directors of satellite Saúde Criança sites within Brazil; physicians at the public Hospital da Lagoa who refer families to Saúde Criança; Arminio Fraga, economist and president of the Saúde Criança Trust Fund; Rick Martinez, Director of Corporate Contributions at Johnson & Johnson, a financial partner of Saúde Criança for the last six years; program staff, particularly Leticia Isnard, director of methodology; program volunteers; and selected program participants. If possible, it would also be ideal to speak to a representative from the Ashoka Foundation as Ashoka has awarded several international awards to Saúde Criança over the last twenty years. Key questions for each of the stakeholder groups will be different based on their perspective. It will be important for the evaluator to not only hear the individual perspectives of the different groups, but also maintain an overarching question of understanding the essence of Saúde Criança that contributes to both strengths and weaknesses of the program, as the intention is to replicate this program in settings outside of Brazil. Key questions for each group are outlined below. It is important to note that the nature of this evaluation is qualitative (therefore iterative) and ongoing, therefore questions (and the evaluator) must remain flexible to adapt to input from the respective stakeholder groups and understand that questions may evolve parallel to the evaluation process.

For the CEO/Founder, COO, and Program/Site Directors: What are the strengths of Saúde Criança? What are the current weaknesses? How is Saúde Criança supposed to work? What do they see as the most crucial components of the program that lead to tangible impact? What would they change?

For physicians at referring hospitals: Why did they choose to refer a family to Saúde Criança? What is Saúde Criança's role in patient care? How does Saúde Criança make a difference from a clinical perspective? What is the next-best alternative to Saúde Criança?

For funders/financial directors: What motivated them to donate to Saúde Criança? How are the funds mainly used? Were the funds used effectively to their knowledge? How will funds maintain future efforts?

For the program staff: How are activities executed? How are different components of the Family Action Plan recorded? How are they communicated between staff members? How can activities be improved? How are areas of need for families identified? What is unique about the range of activities that leads to tangible impact for participants?

For program volunteers: What motivates you to volunteer? How is your role evaluated? How do you communicate potential problems with monthly evaluations to program staff members/coordinators? What are the strengths of Saúde Criança? What are the weaknesses of Saúde Criança?

For program participants: How long have you been receiving support from Saúde Criança? What have you gained? What do you feel that you are missing or not receiving from Saúde Criança? If there was something you could change about Saúde Criança, what would it be?

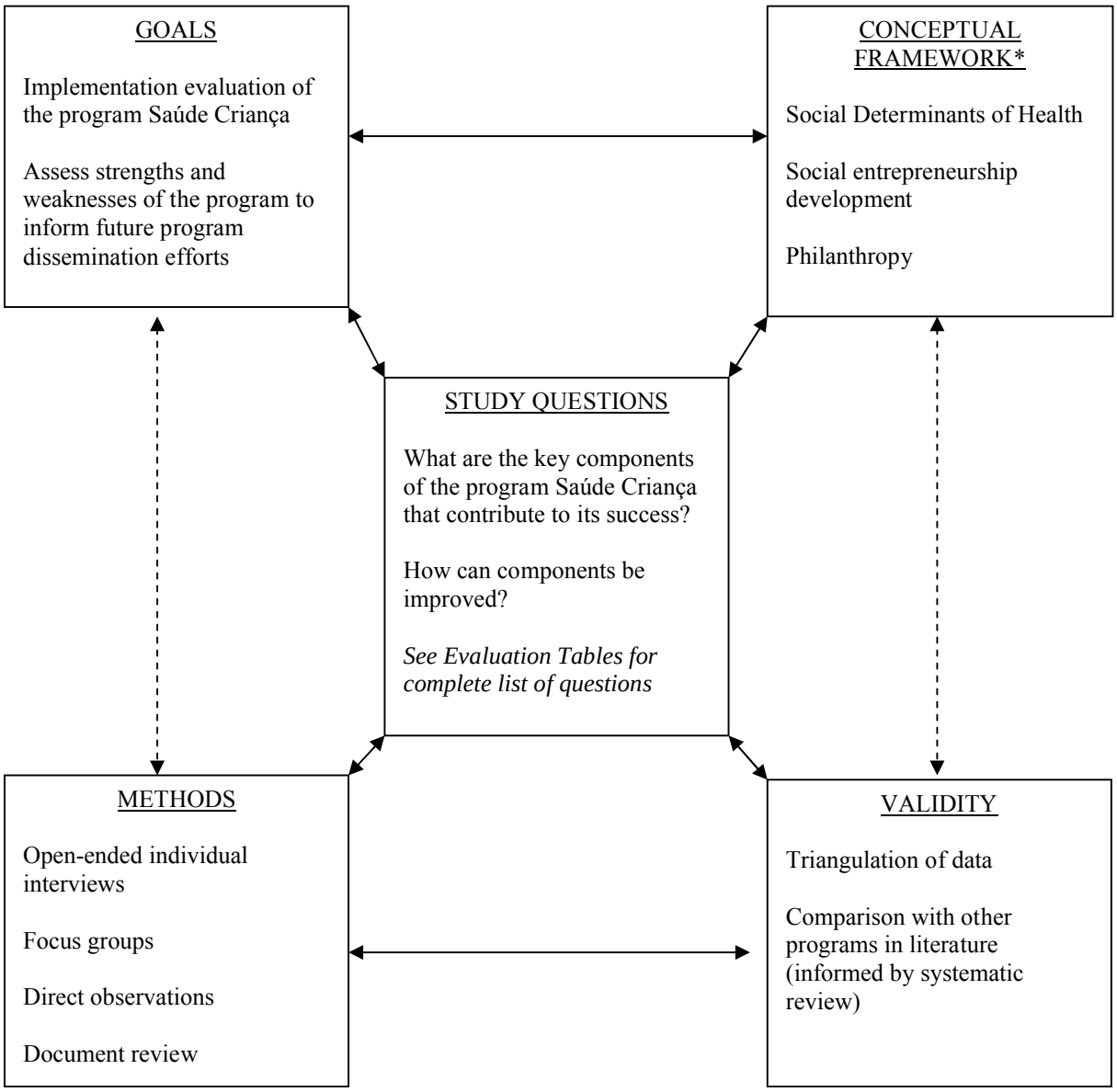
Challenges are inherent to any evaluation, particularly if or when it occurs in a foreign context to the evaluator. I envision the greatest challenge to be time. Useful and quality evaluations of a program in existence for twenty years could take years in itself, especially when multiple stakeholders are involved. Ensuring independent perspectives from program staff members versus program volunteers I also envision as a challenge as the organizational culture of the program is extremely collaborative. How to capture potential intermediate outcomes of participants/families that occur along a spectrum or are not necessarily quantifiable (i.e. self-capacity, internal family infrastructure) may prove challenging as well.

Additionally, the evaluation plan laid forth will ideally cross countries and potentially function in a range of contexts beyond Rio de Janeiro, Brazil, as the program disseminates. While the role of an internal evaluator familiar with context at each site is invaluable, an external evaluator will wrestle with the realities of executing the program in low-resource settings. Compromises and at times conflict will be inevitable however quality and sustainability should remain priorities of any evaluator. An awareness of these challenges will contribute to Saúde Criança's ongoing success.

Evaluation Design

Successful and useful evaluations are sensitive to available resources, the input of stakeholders, and feasibility of evaluation activities. Evaluation of the implementation of Saúde Criança will be completed using a *qualitative study design*. This type of study design will provide detailed, descriptive information about what the program is doing and how the program leads to desired outcomes, paying attention to inputs, activities, processes, and structure[27]. The nature of a qualitative design allows for a reflexive and iterative process throughout the evaluation, informed by both the evaluator and the program stakeholders. The evaluation design

is depicted below in Figure 2. This model is borrowed from John Maxwell's Interactive Model of Qualitative Research Design and consists of five components: Goals, Conceptual Framework, Research Questions, Methods, and Validity[28]. I selected this model to guide the evaluation design because it emphasizes the interactive nature of a qualitative approach in two distinct ways: First, the design model itself is interactive; each of the components has implications for the others, rather than the components being in a linear, unidirectional relationship with one another. Second, the design allows for change in response to the circumstances under which the evaluation is being conducted, rather than simply being a fixed determinant of research practice. To increase the validity of this evaluation, data will be collected from multiple sources and compared for similarities and/or differences as indicated in the evaluation tables (triangulation).



* may evolve as evaluation unfolds

Figure 2: Design Map for the Evaluation of the Saúde Criança Program

SOURCE: Adapted from *Qualitative Research Design: An Interactive Approach*, by J. A. Maxwell, 2005. Copyright by SAGE.

Evaluation Methods

Qualitative methods lie at the core of this implementation evaluation. They provide an understanding beyond numbers of *how* the program achieves its level of impact. These methods include open-ended individual interviews, focus groups, direct observations, and document review. The skill and experience of the evaluator cannot be underestimated to execute a detailed and involved evaluation. *Open-ended interviews* with program participants and members of program staff will provide the majority of data to assess how the components of the Family Action Plan (FAP) function and interact to create improved outcomes for program participants. These interviews must be open-ended to capture different perspectives without predetermining them through selection of questionnaire categories[27]. They will also provide insight into what the local personnel identify as strengths or weaknesses of the different program components. *Focus groups* with the individual coordinators (i.e. Social Work, Nutrition, Psychology, Legal Services) will "take advantage of the group dynamic…[and] lead to discussions and revelations of new information"[21]. As mentioned in previous sections, the nature of the Saúde Criança staff is collaborative. Focus groups will allow the evaluator to not only gain a holistic perspective of the group dynamic, but also provide a separate means to confirm or disconfirm data collected in individual interviews. All interviews and focus groups will be audio recorded and transcribed for content analysis.

Direct observations include description of activities as they occur, behaviors, interpersonal and organizational processes within the program. By nature, observations are subjective therefore familiarity with the Saúde Criança model and physical space will help inform useful observations. These observations will be particularly important to document communication between program staff and participants and amongst program staff members.

These observations will capture a sense of "program culture" that is inherent to process-related outcomes. Lastly, *document review* refers to reviewing program-related material. These documents may range from activity logs (i.e. visits with particular services within the program), program literature written for public distribution, and Nutrition, Psychology, or Social Work reports of or for participants. Document review may also include each participant's log of visits as maintained by the Attendance Team Coordinator.

In two specific instances, quantitative methods will be used to provide objective measurements alongside qualitative data. These include: 1) pre/post test surveys to measure sense of self-efficacy of participants as well as to measure if participants have an increased commitment to education and psychological support before and after participation in the program Saúde Criança; and 2) reviewing numerical trends of pediatric hospitalizations of program participants from the affiliated hospital health records or database. The method or combination of methods is assigned to specific evaluation questions as indicated in the Evaluation Tables.

IRB Considerations

The implementation evaluation to be conducted in June 2012 was submitted to the UNC Institutional Review Board in April 2012 for review by the principal evaluator. The study was determined to be exempt from further review according to the regulatory category under 45 CFR 46.101(b). The full IRB application can be found in Appendix C.

Evaluation Planning Tables

Short Term Objective 1: *All children ages 0-10 years up to date on vaccinations.*		
Evaluation Questions	**Participant**	**Method(s)**
Are all children 0-10 years up to date on vaccinations?	Attendance Team	Open-ended interviews; document review
What resources are available to complete vaccinations for participants?	Attendance Team; Program Participant	Open-ended interviews
How long does it take to achieve completed vaccination status?	Attendance Team	Open-ended interviews
How are vaccinations recorded? How is a child's immunization status communicated to other staff members?	Attendance Team; Social Work Coordinator	Open-ended interviews; document review; direct observation
Are there barriers to completing vaccinations?	Social Work Coordinator; Program Participant	Open-ended interviews
What can be improved to ensure appropriate vaccinations?	Attendance Team; Social Work Coordinator	Open-ended interviews

Short Term Objective 2: *Adequate nutrition status of all children.*		
Evaluation Questions	**Participant**	**Method(s)**
Have all children obtained adequate nutrition status? If no, why not?	Nutritionist	Open-ended interviews; document review
How is nutrition status monitored and recorded?	Nutritionist	Open-ended interviews; Document review
How do participants receive adequate nutrition supplies?	Nutritionist; Program Participant	Open-ended interviews
Who decides allocation of nutrition supplies?	Nutritionist	Open-ended interviews
How are concerns about nutrition status communicated between staff members?	Nutritionist; Social Work Coordinator	Open-ended interviews; direct observations
What can be improved to ensure adequate nutrition status?	Nutritionist; Attendance Team; Program Participant	Open-ended interviews

Short Term Objective 3: *Improved housing conditions so that each household has a home meeting basic living requirements including: running water, treated sewage, painted walls, roof without leakages, and a bathroom with flush toilet, sink, and shower.*		
Evaluation Questions	**Participant**	**Method(s)**
Does each household have adequate housing conditions? If no, why not?	Social Work Coordinator; Program Participant	Open-ended interviews
How are housing assessments addressed?	Social Work Coordinator	Open-ended interviews
Who completes housing improvements?	Social Work Coordinator	Open-ended interviews
How are housing projects monitored and completed?	Social Work Coordinator; Attendance Team	Open-ended interviews
Are there barriers to completing housing projects?	Social Work Coordinator; Program Participant	Open-ended interviews
How can housing projects be improved?	Social Work Coordinator	Open-ended interviews

Short Term Objective 4: *Increased sense of self-efficacy for head(s) of household*		
Evaluation Questions	**Participant**	**Method(s)**
Does the head of household have an increased sense of self-efficacy?	Program Participant	Pre- and post-test surveys
How often is self-efficacy measured or monitored?	Psychologist; Attendance Team	Direct observations
How can each head of household receive more self-efficacy support?	Psychologist	Open-ended interviews
How are concerns of participant self-efficacy communicated amongst staff members?	Psychologist; Attendance Team; Social Work Coordinator	Open-ended interviews; Direct observations

Long Term Objective 1: *Each family is self-sustainable and no longer requires assistance from SAÚDE CRIANÇA.*		
Evaluation Questions	**Participant**	**Method(s)**
Has the family "graduated" from Saúde Criança (i.e. independent of Saúde Criança support)? If no, why not?	Attendance Team; Social Work Coordinator	Open-ended interviews
How do the different Family Action Plan (FAP) components combine to create self-sustained families? Provide examples.	Program Director; Referring Physician; Program Staff (Nutritionist, Psychologist, Legal Services Consultant, Social Work Coordinator)	Open-ended interviews; Direct observation
How are unmet FAP goals addressed?	Program Director; Social Work Coordinator	Open-ended interviews
What strategies have been successful in encouraging participant graduation?	Program Staff (Nutritionist, Psychologist, Legal Services Consultant, Social Work Coordinator)	Open-ended interviews
What strategies have been unsuccessful in encouraging participant graduation?	Program Staff (Nutritionist, Psychologist, Legal Services Consultant, Social Work Coordinator)	Open-ended interviews
Are there gaps in services provided?	Program Director; Social Work Coordinator	Open-ended interviews
What program resources/activities are most essential for successful family graduation?	Program Director; Program Staff (Nutritionist, Psychologist, Legal Services Consultant, Social Work Coordinator)	Open-ended interviews

Long Term Objective 2: *Increased awareness and importance to education and psychological support within families.*		
Evaluation Questions	**Participant**	**Method(s)**
Do enrolled families have an increased commitment to education and psychological support? If no, why not?	Program Participant; Psychologist	Pre- and post-test surveys; Open-ended interviews
After graduating from Saúde Criança, do staff members monitor a family's status/progress? If so, for how long? Are families allowed to re-enter into Saúde Criança?	Program Director; Social Work Coordinator	Open-ended interviews
Does increased psychological support for families lead to reduced pediatric hospitalizations?	Program Director; Social Work Coordinator	Open-ended interviews; Health records/hospital database
How do education and psychological support contribute to Saúde Criança's success? Please provide examples.	Program Director; Program Staff	Open-ended interviews

Long Term Objective 3: *Families will make healthier lifestyle choices.*		
Evaluation Questions	**Participant**	**Method(s)**
Do families make healthier lifestyle choices?	Program participant(s); Social Work Coordinator	Pre- and post-test surveys; document review
How are healthier lifestyle choices communicated to families?	Attendance Team; Program Staff (Nutritionist, Psychologist, Legal Services Consultant, Social Work Coordinator)	Open-ended interviews; Direct observations
How can families be more empowered to make healthier lifestyle choices?	Program Director; Program Staff (Nutritionist, Psychologist, Legal Services Consultant, Social Work Coordinator)	Open-ended interviews; focus group with program staff
What are the resources within Saúde Criança to encourage healthier lifestyle choices? How can they be improved?	Program Director; Program Staff (Nutritionist, Psychologist, Legal Services Consultant, Social Work Coordinator)	Open-ended interviews; focus group with program staff
What are the challenges to providing healthier lifestyle choices?	Program Director; Program Staff (Nutritionist, Psychologist, Legal Services	Open-ended interviews; focus group with program staff

	Consultant, Social Work Coordinator)	

Dissemination Plans

Dissemination of the results of this program evaluation is essential for two main reasons: 1) to inform the program itself of strengths/weaknesses of their methodology in its current state and 2) to inform future efforts of program expansion to locations outside of Brazil. An effective evaluation should provide "usable" information – "information that project staff and other stakeholders can utilize directly to make decisions about the program"[25]. This evaluation takes place at a formative time as Saúde Criança has secured funding and a partnership to launch a pilot model in Bogota, Colombia, by January 2013. Therefore, findings from this evaluation will be compiled in a written evaluation report available in three languages: Portuguese, Spanish, and English. Ideally information from this report will be used in future Saúde Criança brochures and promotional literature, and if approved by the program CEO, made publically available on their website.

Similar to the design of this evaluation, the communication of findings and results must be an iterative process to ensure transparency and focus of the evaluation. From the onset of the evaluation, I will discuss the dissemination goals with program staff and stakeholders to ensure their co-ownership of the process and how to best apply results. Weekly meetings with the Saúde Criança executive team while on-site in Rio will allow for this communication and provide an avenue for me as an evaluator to present preliminary results from the qualitative analysis as the evaluation progresses.

Lastly, I am hopeful that this evaluation report will generate new knowledge and awareness about effective programming in low-resource settings of the developing world. While

Saúde Criança continues to raise large amount of funding from numerous philanthropic organizations (Ashoka, Skoll Foundation, etc), to date there are no published articles describing the design, impact, or evaluation of the Saúde Criança model in peer-reviewed journals or other more academic outlets. Even though organizations such as the CDC and WHO have published literature on the importance of addressing social determinants of health to improve population health outcomes, what is lacking is real-world examples of *how*. Saúde Criança represents a feasible and effective intervention that can be taken to scale globally. Publishing their story, growth, and evaluation in a peer-reviewed global health journal or at appropriate national/international conferences is a key component of the dissemination effort.

V. DISCUSSION

At the heart of the concern with social determinants of health, and health inequity, is concern for people without the freedom to lead flourishing lives[29]. To make a fundamental improvement in health equity, technical and medical solutions such as disease control and clinical care are, without doubt, necessary. But they are insufficient. Associacao Saúde Criança is a non-governmental organization that addresses the root cause of inequitable health outcomes through an innovative methodology for many of Brazil's most vulnerable communities. Their approach aligns with the WHO's Social Determinants of Health Conceptual Framework which advocates for action in the following three main areas: (1) Improve conditions of daily life such as the circumstances in which people are born, grow, live, work and age; (2) Tackle the inequitable distribution of power, money and resources, or the structural drivers of those conditions of daily life; and (3) Measure the problem, evaluate action to expand the knowledge base, and raise public awareness about the social determinants of health.

Through the process of writing this paper and conducting formative fieldwork, I have learned several lessons pertinent not only to future program implementation of the Saúde Criança model, but also to my personal public health perspective. First, before even thinking about interventions, it is imperative to gather the evidence and establish the baseline. These are needed to guide program development and, equally important, to support the public and institutional information sharing that will be paramount for any progress in addressing the social determinants of health. Once the program gets started, systematic monitoring and repeated evaluations are indispensable for continuously adjusting and refining the program design, as well as for keeping key stakeholders and the public abreast with the progress and challenges.

Second, poverty is multidimensional problem, and therefore requires a multidimensional solution. Reducing inequities through influencing the social determinants is a values-based endeavor that needs careful mapping of perspectives and vested interests of key actors. It also calls for a change in the incentives and the attitudes of staff across multiple sectors and organizations at the local and facility levels. However, it is important to realize that, ultimately, the final battle for health equity takes place in the public space. Through creative multimedia applications, intelligent use of the evidence and strong intersectoral partnerships, influencing the public debate is within the reach of the health sector.

Third, the role of leadership and a committed team cannot be underestimated when formulating and carrying out a vision to create social change. Leadership is required to mobilize sectors and organizations to integrate and internalize the goals and objectives within the respective structures and action plans of these sectors. Particularly relevant to the health sector, leadership is required to push programs outside traditional boundaries of delivery and urge society to re-examine our definition of improved health outcomes and how they are measured.

Lastly, context, as always, matters. Evaluation is invaluable for program growth and expansion however the design and respective execution will inevitably evolve to cater to the norms and constrains of its respective context. Evaluators must be persistent, ready to adapt, and focused to ensure meaningful contribution to both a program and the greater evidence base at large. These skills were essential to carry out the process evaluation described in Section IV, which revealed four major themes articulated across stakeholders to be key elements of Saúde Criança's success[30]: (1) strict execution of the Family Action Plan, (2) shared accountability between families served and NGO staff, (3) fiscal and social transparency, and (4) a shared ideal of enabling families to become self-sufficient. These elements are essential for future

dissemination efforts for Saúde Criança and provide guidance for other programs that seek to address social determinants of health.

After twenty years in practice, Saúde Criança serves as a bridge at many different levels: between public health and medicine; between marginalized communities and their rights as civil members of society; and between the private and public sectors. Their public health impact is tangible, and their methodology holds great potential to reduce disease burden due to poverty throughout the world. I am hopefully that the literature reviewed here, as well as the program and evaluation plans provided will help inform future implementation and evaluation of their model beyond Brazil's borders.

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VII. APPENDIX

Figure 1: The Commission of Social Determinants of Health Conceptual Framework

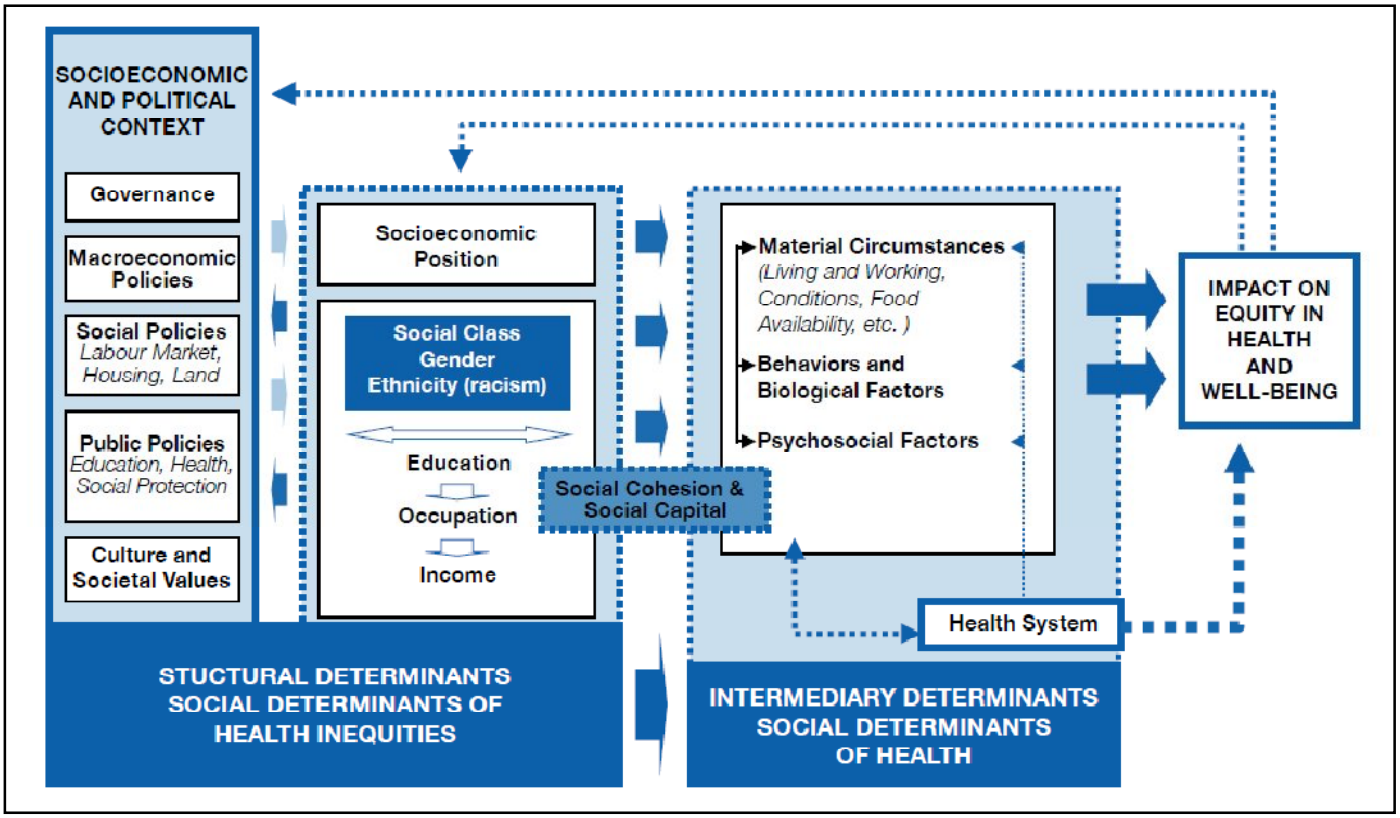

Table 1: Summary of Articles Included in Systematic Review

Program	Goal	Activities	Evaluation	Outcomes
Bolivian Social Investment Fund	Promote sustainable development in poor areas by providing direct investments in health, education, and sanitation	Education investments: Repaired schools or constructed new ones; improved condition of classrooms Health investments: Repaired existing health centers, increased medicine supply and equipment; motorcycle to inc home visits; radio to contact other health centers; solar panels for electricity Sanitation investments: Small-scale potable water systems; training of community-health workers	1993 baseline and 1997 follow-up surveys of data; impact evaluation of investments; experimental design based on randomization or matched comparison Different methodologies for different projects based on resource and timing constraints Demonstrated how evaluation design can evolve between baseline and follow-up stages when interventions are not implemented as planned	Education: improved infrastructure, minimal impact on educational outcomes Health: raised utilization rates and associated with substantial declines in under-age-five mortality Sanitation: no major impact on water quality until combined with community-level training; did increase access to and quantity of clean water → decline in under-age-five mortality
Progresa	Incentive-based, federal welfare program to develop human capital in low-income households; invest in nutrition, health, and education for children of low-income families to break intergenerational continuation of poverty	Cash transfers every two months based on compliance with school attendance, preventive health care visits (immunizations, well-child care, pre/post natal care, etc), and nutrition and health education sessions Provide micro fortified food supplements	Randomization effectiveness study to measure short-term nutritional impact; measuring height and rates of anemia Included intermediate outcome of papilla intake High rate of crossover families from control to intervention arm due	Age- and length-adjusted height greater by 1.1 cm (26.4 cm in the intervention group vs 25.3 cm in the crossover intervention group) mean hemoglobin values higher in the intervention group (11.12 g/dL; 95% [CI], 10.9-11.3 g/dL) than in the crossover

		(*papilla*) to mothers	to political pressure	intervention group (10.75 g/dL; 95% CI, 10.5-11.0 g/dL) no differences in hemoglobin levels between the 2 groups at year 2 after both groups were receiving the intervention
Integrated Management of Childhood Illness Strategy	WHO+UNICEF strategy with 3 main components: improve the performance of health workers in first-level facilities; ensure health systems support for child health; strengthen family practices needed to prevent disease and improve home care for sick children	Introduction phase: Training key decision-makers, defining management structure, building government committee Early implementation phase: Experience with implementing IMCI in limited geographical areas to develop national plan; culminates with review meeting Expansion phase: Increase range of IMCI interventions and IMCI coverage	Evaluation of IMCI strategy in three countries to assess efficacy of implementation (Brazil, Peru, Tanzania) Two complementary methodologies: (1) Desk reviews and interviews w/key informants (2) statistical analyses of district characteristics associated with IMCI implementation; ecological design to compare spatial distribution of IMCI implementation with potential explanatory variables, including sociodemographic factors, health infrastructure and pre-implementation child health and nutritional status.	Brazil: uptake by poor and small municipalities and those further away from the state capital was significantly lower. Peru: no association with distance from Lima, and a non-significant trend for IMCI adoption by small and poor departments. Tanzania: only statistically significant finding was a lower uptake by remote districts. Implementation not associated with baseline mortality levels in any country studied

Appendix A: Family Action Plan Implementation

Assistance Stages

Stage 1: Selection in the affiliated public institution

The program should create a single entry criterion for participation in the program, and all participants must join the program via referral from the affiliated public institution. For example, the criterion of ASC is *"a child hospitalized or recently discharged from the public Lagoa Hospital in Rio de Janeiro, Brazil, whose family's psychosocial situation places the child at risk."*

The selection of the child and thus family to be assisted is made by the professional staff of the affiliated public institution according to agreed criteria between it and the program. The child and his/her respective family are then referred to the program.

Responsible Party: To be selected
Participants: Affiliated public institution professionals
Document: Referral Form, completed by a participant
Selection: Daily, according to the needs

Stage 2: Reception at the NGO

A – Registration

The Operational Coordinator of the program will receive the responsible family member of the child and/or child (if able to be present) and registers the information from the Referral Form into a database in order to begin the assistance process. The Operational Coordinator opens a file for the new family and directs them to the Social Work team for the initial evaluation. Once complete, the family will attend the program monthly to receive support in Nutrition, Psychology, Psychiatry, Social Service, Legal Services, and Professional Training. These monthly meetings are also used to assess and record the family's progress, update and/or amend the Family Action Plan (FAP) when necessary.

Responsible Party: Program Operational Coordinator
Participants: Referred family
Document: Referral Form
Attendance: Days and schedule to be determined

B – Initial Evaluation

The following evaluations are conducted in an interview format between the responsible party of the family to be assisted and professional members of the ASC team.

Social Work Evaluation

A member of the Social Work team will interview the responsible party to determine his/her participation according to the *Basic Criterion of Participation* in *Attendance of ASC*. For families that do not meet enrollment criteria, the interviewer must justify the reasons to the responsible party and record so on the Referral Form. The family will be guided back to the person of referral from the affiliated public institution.

For families that do meet enrollment criteria, the interviewer will officially register the family in the Database and provide the family with its Family Notebook that will contain the family's monthly meeting dates. The interviewer is responsible for explaining the process and goals of the program as well as the rights and responsibilities of the participating family. He/she will open an Initial Evaluation Form, record the basic needs of the family, record any material needs in the Basic Benefits Record (i.e. diapers, food, filters, etc.), and schedule the obligatory initial domiciliary visit within 30 days.

Once Social Work has completed their section of the Initial Evaluation Form, the family is guided with the printed form to the professionals of each subsequent section (i.e. Nutrition, Psychology, Professional Training) to assess the family's needs in each respective area.

Responsible Party: Social Work Initial Evaluation Coordinator
Participant sections: Social Work
Documents: Initial Evaluation Form, Family Notebook, and Basic Benefits Record
Attendance: To be determined

Nutritional Evaluation

A professional nutritionist will complete and record the child's Nutritional Evaluation, including his/her weight, height, and nutritional classification (malnutrition, healthy, overweight, obese). If the child is physically unable to be present at the program, the Nutritionist will provide a Nutritional Monitoring Record to be completed by a health professional who can access the child.

Based on an interview with the responsible party, the nutritionist will assess and prescribe any food supplies (i.e. vitamin-enriched milk, vitamin supplements, etc.) that the family will receive from the NGO.

The nutritionist will complete his/her evaluation and record the Nutritional Diagnosis and the need for monthly or quarterly monitoring in the family's FAP. The family is then guided to the Psychology section.

Responsible Party: Nutritionist
Participant sections: Nutrition
Documents: Initial Evaluation Form, Nutritional Monitoring Record, and FAP
Attendance: To be determined

Psychological Evaluation

A professional psychologist will evaluate the psychological state of the responsible party, indicating the need or not of psychological monitoring in the family's FAP. The psychologist will schedule the responsible party's participation date in the obligatory Reception Group (see Monthly Attendance section) and will record it in the FAP and in the Family's Notebook. Once the initial psychological evaluation is complete, the family is guided to a Professional Training Coordinator.

Responsible Party: Psychologist
Participant sections: Psychology
Documents: Initial Evaluation Form, FAP, and Family Notebook
Attendance: To be determined

Professional Training Evaluation

A Professional Training Coordinator will assess the need of formal job training for eligible adult family members and will analyze which member presents the greatest potential. A mother's professional training is preferred, however opportunities are not exclusive for women. If participation is confirmed it is recorded in the FAP and further information will be provided to the family (see Complement Programs section). A maximum of two people per family are eligible for training. Exceptions must be authorized separately.

Responsible Party: Professional Training Coordinator
Participant sections: Professional Training
Documents: Initial Evaluation Form and FAP
Attendance: To be determined

Stage 3: Initial Home Visit

The initial home visit is the final component of the Initial Evaluation. During this visit, member(s) of the Social Work team will analyze the environment of the home and the family's composition, record the status of all water and electronic installations, collect data of the family's socioeconomic situation, and complete the Housing section of the Initial Evaluation Report. Any perceived repair needed for the home will be recorded in the FAP so that future action steps to provide aid can be taken.

Responsible Party: Social Worker
Participant sections: Social Work
Documents: Initial Evaluation Form and FAP
Attendance: Ongoing as needed

Stage 4: Creating the Family Action Plan (FAP)

The FAP is the core of the ASC model and is essential to create long-lasting social impact. Each family's FAP is created after the completion of the initial evaluation and upon the first return of the family by a social worker and the responsible party for the assisted child (see form in appendix). The goals, commitments, responsibilities, and action steps are customized to the needs of each family, and are monitored and evaluated on a monthly basis.

Responsible Party: Attendance Team Coordinator
Participant sections: Social Work
Documents: FAP
Attendance: First monthly attendance

The FAP is composed of five targeted areas, each with its specific goals and actions. The action steps are tailored to the need of the family by a social worker. Each action contains a planned date, date of accomplishment, and notes section to be completed by interviewers during the monthly attendance. Below is an example:

Action	Planned Date	Date of Accomplishment
Complete Vaccination Record	February / 2007	April / 2007

Each area contains a group of indicators that will serve as a way to measure the family's progress during and after its participation with the program. A newly founded program site may adjust the components of its FAP based on the needs of the families served and according to the local context of the institution. Each family will receive assistance for approximately 2 years and does not "graduate" from the program until the outlined goals of his/her FAP are achieved. Illustrated below are the FAP components as executed by ASC:

1) HEALTH

- To attend to the child and his/her family during the process of medical treatment until the health of every child in the family is at least in satisfactory clinical condition
- To assist in appointment scheduling and to follow-up with hospital attendances to ensure few or no missed appointments
- To monitor the child and family's nutritional behavior, provide nutritional counseling, and record anthropomorphic data (i.e. height, weight)
- To guide and ensure the vaccination of all children per family and secure their regular attendance at an accessible health center
- To provide medications, vitamin-enriched foods, and orthopedic and breathing medical supplies when necessary to aid in the improvement of the child's health condition (i.e. inhaler, air liquefier, crutches, vitamin-enriched milk, etc.)

- To provide psychological and psychiatric counseling and support of all family members
- To provide educational courses on hygiene, family planning, substance abuse, violence, domestic accidents, and child development

2) EDUCATION

- To mandate and guide the enrollment of all children between the ages of 0-10 per family in a school

3) HOUSING

- To evaluate a family's housing condition
- To provide training, tools, and donated labor to refurbish a family's home so that it meets health standards
- To ensure that all water and electric installations are in good condition
- To assist a family in obtaining property documents when applicable

4) CITIZENSHIP

- To guide family members in obtaining necessary citizenship documents and/or government benefits when applicable
- To offer educational lectures related to citizenship and rights of citizens

5) INCOME

- To provide eligible family members professional training and/or reference to employment opportunities so that at least one adult in the family is working and has a formal or informal minimum wage
- To offer participation in entrepreneurial events

Stage 5: Monthly Attendance

Once the FAP is created, the responsible party for the child assisted is required to attend the program monthly to receive benefits as well as an evaluation of their progress in his/her respective Family Action Plan (FAP). Along with professional support in the outlined areas of the FAP, benefits include basic food items, medicines, medical equipment when applicable, water filters, mattresses, clothes, toys, school materials, diapers, condoms and other donations based on a family's needs. All benefits received must be recorded in a database. Transportation costs should be covered by the NGO so that participants are able to make their scheduled appointments and a healthy meal and/or snack should be provided for each responsible party on his/her day of attendance. All transportation vouchers distributed must be recorded in a database.

Upon arrival on his/her monthly meeting, an interviewer from the Attendance Team (volunteers) will listen to and record the responsible party's progress report in the five areas of the FAP. Based on the needs expressed by the responsible party, the interviewer will guide him/her to each respective section (i.e. Legal Services, Social Work, Nutrition, Psychology). The responsible party is informed of his/her next scheduled date by the Social Work team. In order to receive benefits the responsible party must present the Attendance Coordinator with a signature from the interviewer to ensure that s/he has completed a FAP evaluation.

Quarterly throughout the year, interviewers will administer a Periodic Evaluation in order to ensure that all demographic information is up-to-date in the program's database. This is administered along with the PAF and any changes must be submitted for entry in the database.

Responsible Party: Attendance Team
Participant sections: Legal Services, Social Work, Nutrition, Psychology, Professional Training as needed
Documents: FAP
Attendance: monthly

The monthly attendances include professional services provided in the following areas as needed and outlined in each family's FAP. All services and benefits provided are recorded in a database. Below are the responsibilities of each section:

Social Work:

- To identify new families needing assistance and coordinate the initial evaluation
- To create the initial FAP with the responsible party of the family
- To ensure all children in each assisted family ages 0-10 years are enrolled in school
- To coordinate *Project Heal, Project Home,* and the *Adolescents Group*
    - *Project Heal*: To provide one-hour educational lectures for the responsible party of the family on his/her day of attendance in order to promote family self-sustainability. Topics are selected based on the perceived need of families assisted and can include, but are not limited to, domestic violence, family planning, hygiene, stress management, etc. Topics change monthly or periodically throughout the year as decided by the Social Work team.

- *Project Home*: To provide the resources and aid necessary to restructure a family's home so that it meets the goals of the FAP.
- *Adolescents Group*: To provide sexual education to adolescents of assisted families through bimonthly meetings and interactive activities. Transportation and food should be provided by the program for all participants.

Psychology:

- To provide counseling to family members and evaluate their emotional status so that each member's health status meets the goals of the family's FAP.
- To coordinate the *Reception* and *Reflection Groups*
  - *Reception Group*: To introduce the responsible party of each new family to the mission, vision, and work of the program. Sessions are held monthly for all new families of that month and are obligatory for families to receive benefits.
  - *Reflection Group*: For families who have achieved one year of participation with the program, to evaluate the family's progress, commitment, and reflect on the activities of the past year through an open-ended reflection session with the responsible party of the family. The psychologist will also begin to prepare the family for the closing process.

Nutrition:

- To conduct monthly nutritional assessments of the assisted child and record height/weight data.
- To provide counseling and education on healthy eating habits.
- To prescribe specific vitamin-enriched food benefits (i.e. milk, supplements) when necessary that a family will receive upon fulfilling its responsibilities.

Income

- To create and provide job training opportunities
- To identify and recruit eligible family members for professional opportunities
- To record attendances and absences and monitor the progress of participants

Citizenship

- To educate and assist families in obtaining citizenship documents, government benefits (i.e. welfare programs), and identification documents for all family members
- To provide legal counseling when necessary

Appendix B: Program Logic Model

RESOURCES	ACTIVITIES	OUTPUTS	OUTCOMES	IMPACT
In order to accomplish our set of activities we will need the following:	*In order to address our problem or asset we will conduct the following activities:*	*We expect that once completed or underway these activities will produce the following evidence of service delivery:*	*We expect that if completed or ongoing these activities will lead to the following changes in 1-3 then 3-5 years:*	*We expect that if completed these activities will lead to the following changes in 7-10 years:*
Public hospital affiliation Volunteers for monthly meetings with participants The Family Action Plan (FAP) Initial funding (incorporation fees) Transportation vouchers Staff members in each domain of FAP Computer to initiate database Inventory of basic supplies (diapers, formula, water filters, toys, mattresses, condoms, medical devices if available, condoms, other donations, etc) Fundraising Committee	Receive hospital referrals Train volunteers Initial evaluation to identify needs of individual families and determine enrollment in program Home visits Monthly meetings in each of the five areas of the FAP for each enrolled family: -Health -Education -Housing -Income -Citizenship Distribute supplies as needed per family Ongoing fundraising events, local and international Apply for international grants (Skoll Foundation, Ashoka, Gates Foundation)	Develop a FAP tailored to the needs of each family, recorded in database Trained volunteers as successful monthly evaluators Home visits for enrolled families completed and recorded Qualified adults enrolled in vocational training courses Local and international awareness/funding received	*Short Term (1-3 years)* All children 0-10 up-to-date on vaccinations Adequate nutrition status for all children of a family Improved housing conditions All school-aged children attending schools Social welfare and household claims documents up-to-date Income exceeding the minimum standards for up to 4 members; increased by ¼ total household income for each member above 4 Increased sense of agency and self-esteem for head(s) of household *Long Term (3-5 years)* Increased system of support for households below poverty line Continuing secondary education of children within family unit	Reduced disease burden due to poverty Reduced rate of pediatric hospitalizations Increased number of self-sustainable families in low-resource settings Increased global awareness of the FAP methodology to break the link between poverty and poor health

			Increased awareness and importance to education and psychological support Replicated model at public hospitals throughout Brazil and beyond	

Appendix C: IRB Application

IRB Number: 12-0641	Initial	Principal Investigator: Neeti Doshi

General Information

1. General Information

1.Project Title

Holistic Health Models for Low Income Populations: Lessons Learned from Brazil

2.**Brief Summary**. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Purpose: To plan the implementation and evaluation of the dissemination of the Saude Crianca model to applicable settings outside of Brazil.

Participants: Saude Crianca staff, local hospital physicians, program planners, program participants, and stakeholders.

Procedures (methods): Qualitative interviews and analysis.

3.Is this new study similar or related to an application already approved by a UNC-Chapel Hill IRB? Knowing this will help the IRB in reviewing your new study.

No

2. Project Personnel

1.Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

Yes

This study will require the identification of a single faculty advisor, who should be added in Project Personnel on this page. This should be the faculty member who will mentor this research, who may or may not be your academic faculty advisor.

The faculty advisor will be required to co-certify with the student/trainee PI. You should also make sure this person has a chance to review and edit the submission before you submit.

Choose the status of the student/trainee:

graduate or professional

2.List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Last Name	First Name	Department Name	Role (with the exception of 'Other,' all roles will have access to edit the application)	Detail
Doshi	Neeti	Public Health Leadership Program	Principal Investigator	view
Calleson	Diane	Public Health Leadership Program	Faculty Advisor	view

Sloane	Philip	Family Medicine	Other	view

NOTE: The IRB database will link automatically to UNC Human Research Ethics Training database and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3.If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Public Health Leadership Program

3. Funding Sources

1.Is this project funded (or proposed to be funded) by a contract or grant from an organization external to UNC-Chapel Hill?

No

2.Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?

Yes

Internal UNC Chapel Hill funding

Department Name	Account Number	Detail
Medicine		view
Institute for Study of the Americas		view

3.Is this research classified (e.g. requires governmental security clearance)?

No

4.Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

✔	Grant Application
✘	Industry Sponsor Master Protocol
✘	Student Dissertation or Thesis Proposal
✘	Investigator Initiated Master Protocol
✘	Other Study Protocol

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

The first question is whether this is RESEARCH

1.Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

Yes

The next questions will determine if there are HUMAN SUBJECTS

2. Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

Yes

3. Will you be using identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

No

The following questions will help build the remainder of your application.

4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? If yes, this application will be reviewed by the CTRC and additional data will be collected.)

No

5. Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients **or** does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) **or** does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

No

6. Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)?

Yes

5. Multi-site Study Information

1. Will this study be conducted in locations outside the United States?

Yes

Will your research project involve the Galapagos Islands, Ecuador?

No

If yes, your application will be reviewed by the UNC Center for Galapagos Studies. This Center will be included in routing for approvals after you submit.

Are any of the countries on the U.S. State Department Travel Warning List? See list found at http://www.travel.state.gov (look for "Travel Warnings"). See also the University policy at http://provost.unc.edu/policies/UNC%20Travel%20Policy%2010.18.2010.pdf or global.unc.edu for additional information.

No

2. Is UNC-CH taking or being asked to take reponsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH (e.g., as lead site, study headquarters or IRB of record for other sites)?

Yes

When the collaborating site is a GROUP or ORGANIZATION outside of UNC-CH, complete the following information for each site:

Name	City	State	Country	Status of IRB approval	Has or will the external institution agree to rely on the UNC-CH IRB?	Detail
Associacao Saude Crianca	Rio de Janeiro	RJ	Brazil	No site IRB	Yes	view

When the collaborator is an INDIVIDUAL outside of UNC-CH, complete the following information for each individual:

Name	Address (Street, City, State, Zip)	Phone	Email	Detail
N/A	N/A	N/A	N/A	view

3.Describe the role of UNC Chapel Hill and UNC Chapel Hill investigator(s) in this study.

This study will be funded by two grants from the University of North Carolina System, one from the School of Medicine and one from the Institute for the Study of the Americas. Both grants are supporting a UNC-CH MD/MPH Graduate Student (the PI) to travel to Rio de Janeiro, Brazil, to conduct an implementation evaluation of an integrative health model for dissemination to other settings. The student's research efforts will be supervised by two UNC faculty as listed in the IRB.

Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subject.

Exemptions

Request Exemption

Some research involving human subjects may be eligible for an exemption which would result in fewer application and review requirements. This would not apply in a study that involves drugs or devices, involves greater than minimal risk, or involves medical procedures or deception or minors, except in limited circumstances.

Additional guidance is available at the OHRE website. Exemptions can be confusing; if you have not completed this page before, please review this table with definitions and examples before you begin.

1.Would you like your application evaluated for a possible exemption?

Yes

Will your study either involve prisoners as participants or be FDA-regulated?

No

In order to be eligible for exemption, your research must fit into one or more of the following categories. Check all of the following that apply, understanding that most research falls into one or two categories.

Category 1 (click here for guidance and examples)

✖ The research is to be conducted in established or commonly accepted educational settings. Note: This applies to the location where education research will actually be conducted (e.g., public schools) and NOT to your location at a university.

And the research will involve normal educational practices, such as:

✖ Research on regular and special education instructional strategies.

✖ Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2: (click here for guidance and examples)

Does your study involve minors under the age of 18?

No

The research involves the use of one or more of the following

- ✗ Educational tests (cognitive, diagnostic, aptitude, achievement).
- ✓ Survey procedures.
- ✓ Interview procedures
- ✗ Observation of public behavior.

And either or both of the following is true:

- ✓ The information to be obtained will be recorded in such a manner that participants cannot be identified, directly or indirectly through identifiers linked to the participants.
- ✓ Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Explain

No identifying information will be collected of interview participants.

Category 3 (click here for guidance and examples)

Research involves the use of one or more of the following:

- ✗ Educational tests (cognitive, diagnostic, aptitude, achievement)
- ✗ Survey procedures
- ✗ Interview procedures.
- ✗ Observation of public behavior.

And

- ✗ The participants are elected or appointed public officials or candidates for public office.
- ✗ Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4 (click here for guidance and examples)

- ✗ The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

And either of the following is true:

- ✗ The sources of data are publicly available.
- ✗ The investigator records information in such a manner that participants cannot be identified, directly or indirectly through identifiers linked to the participants.

Category 5 (click here for guidance and examples)

- ✘ The project is a research or demonstration project.

Additionally the following must also be true.

- ✘ The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
- ✘ The research is conducted pursuant to specific federal statutory authority.
- ✘ There is no statutory requirement that an IRB review the research.
- ✘ The research does not involve significant physical invasions or intrusions upon the privacy of participants.

The research is designed to study, evaluate, or otherwise examine one or more of the following:

- ✘ Public benefit or service programs.
- ✘ Procedures for obtaining benefits or services under those programs.
- ✘ Possible changes in or alternatives to those programs or procedures.
- ✘ Possible changes in methods or levels of payment for benefits or services under those programs.

Category 6 (click here for guidance and examples)

- ✘ The research involves taste and food quality evaluation or is a consumer acceptance study.

Either of the following is true:

- ✘ Wholesome foods without additives are consumed.
- ✘ If a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe by one of the following agencies:

Please check which of following

- ✘ The Food and Drug Administration.
- ✘ The Environmental Protection Agency.
- ✘ The Food Safety and Inspection Service of the U.S. Department of Agriculture.

Consent Process for Exemptions

1. While the full regulatory requirements for consent do not apply, some exempt research does involve talking to or interacting with human participants. Under these circumstances, there is still the expectation that you will tell people what you are doing and why, and invite their voluntary participation. If this describes your study, then describe the process for obtaining consent from the subjects. This may or may not include a written consent document or script; if you plan to use a written document, please upload as an attachment as the end of this application process.

This study aims to understand the process of the NGO Associacao Saude Crianca (ASC) by way of an implementation or process evaluation of their model. This evaulation will be conducted through qualitative interviews and data analysis with NGO staff, stakeholders, and participants. The purpose of this evaluation is to understand the critical elements that contribute to ASC's impact. No identifying information will be collected, and all participation will be considered voluntary. That is, you may choose to stop the interview at any point. This information gathered from these interviews may be used for organizational or academic publication. By agreeing to participate in this interview, you understand the role of your participation. Please do not hesitate to ask any questions throughout the interview.

Part A. Questions Common to All Studies

A.1. Background and Rationale

1.Provide a summary of the background and rationale for this study (i.e, why is the study needed?). If a complete background and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive background and literature review, including references.

It has long been known that our social environment influences a population's well-being and health outcomes, often most profoundly in the developing world. More recently, The World Health Organization established the Commission on Social Determinants of Health (CSDH) in 2005 to not only improve health globally, but also reduce differences in health outcomes by developing programs and interventions through a "social determinants of health framework." The Commission acknowledges how the bulk of the global burden of disease and the major causes of health inequities, found in *all* countries, arise from the conditions in which people are born, grow, live, work, and age. As an MD/MPH graduate student, I aim to collaborate with a non-profit organization in Brazil that has acknowledged the influence of social context and is improving health outcomes of low income families across Brazil.

Grounded in the principal that illness is not caused by biological factors alone, the Brazilian NGO *Associação Saudé Crianca* (ASC or roughly in English, Child Health Network) improves health outcomes of low-income, critically ill children by providing a family psychosocial and economic self-sufficiency beyond hospital walls. In Rio de Janeiro, one third of the population lives below the poverty line. Founded in 1991 by pediatrician Dr. Vera Cordeiro, ASC exemplifies how innovation achieves better health outcomes in a setting of low resources. Frustrated by the repetitive cycle of hospitalization à poverty à re-hospitalization of children at the public Hospital da Lagoa that serves several of Rio's poorest communities, Dr. Cordeiro shifted her attention to the root causes of the problem: each child's social and environmental context. Her model – the Family Action Plan – combines government, community, and professional support networks that allow a family to provide adequate care to their children after hospital discharge. Completing its twentieth year in Rio, ASC has helped over 10,000 families and decreased the number of pediatric re-hospitalization days by 65%. Their impact is profound, but perhaps more importantly, is transforming the way the medical and public health community in Brazil approaches health burden. Now in practice in over 20 public hospitals throughout Brazil and internationally recognized as a pioneer in preventive health care, they estimate rehabilitating nearly 40,000 families.

This study proposes to execute a implementation evaluation of the ASC model to understand the strengths and weaknesses of the model for future dissemination efforts.

A.2. Subjects

1.Total number of subjects proposed across all sites by all investigators (provide exact number):

15

2.Total number of subjects to be studied by the UNC-CH investigator(s) (provide exact number):

15

3.If the above numbers include multiple groups, cohorts, or ranges or are dependent on unknown factors, or need any explanation, describe here:

No Answer Provided

4.Do you have specific plans to enroll subjects from these vulnerable or select populations:

✘ Children (under the age of majority for their location)
Note that you will be asked to provide age ranges for children in the Consent Process section.
✔ Non-English-speaking
✘ Patients (i.e., have a specific disease, disorder or condition regardless of where they receive their healthcare)
✘ Prisoners, others involuntarily detained or incarcerated (this includes parolees held in treatment centers as a condition of their parole)
✘ Decisionally impaired
✘ Pregnant women
✘ HIV positive individuals
✘ UNC-CH Students
Some research involving students may be eligible for waiver of parental permission (e.g., using departmental participant pools). See SOP 32.9.1
✘ UNC-CH Employees
✘ People who are likely to be involved in abusive relationships, either as perpetrator or victim (See SOP)

5.If any of the above populations are checked, describe how you plan to confirm status in one or more of those groups (e.g., pregnancy, psychological or HIV testing)

While I am modestly fluent in Portuguese, I will be working on site with a translator that speaks both English and Portuguese. Before beginning the interview I will ask the participant which language they prefer, and proceed accordingly.

6.If any of the above populations are checked, please describe your plans to provide additional protections for these subjects

No identifying information will be collected independent of language spoken.

7.Age range of subjects:

Minimum age of subject enrolled	18
	years
Maximum age of subject enrolled	75
» If no maximum age limit, indicate 99	
	years

A.4. Study design, methods and procedures

Your response to the next question will help determine what further questions you will be asked in the following sections.

1.Will you be using any **methods or procedures commonly used in biomedical or clinical research** (this would include but not be limited to drawing blood, performing lab tests or biological monitoring, conducting physical exams, administering drugs, or conducting a clinical trial)?

No

2.Describe the study design. List and describe study procedures, including a sequential description of what subjects will be asked to do, when relevant.

Successful and useful evaluations are sensitive to available resources, the input of stakeholders, and feasibility of evaluation activities. Evaluation of the implementation of ASC will be completed using a *qualitative study design*. This type of study design will provide detailed, descriptive information about what the program is doing and how the program leads to desired outcomes, paying attention to inputs, activities, processes, and structure (Patton, 2002). The nature of a qualitative design allows for a reflexive and iterative process throughout the evaluation, informed by both the evaluator and the program stakeholders. The evaluation design is adopted from John Maxwell's Interactive Model of Qualitative Research Design and consists of five components: Goals, Conceptual Framework, Research Questions, Methods, and Validity (Maxwell, 2005). I selected this model to guide the evaluation design because it emphasizes the interactive nature of a qualitative approach in two distinct ways: First, the design model itself is interactive; each of the components has implications for the others, rather than the components being in a linear, unidirectional relationship with one another. Second, the design allows for change in response to the circumstances under which the evaluation is being conducted, rather than simply being a fixed determinant of research practice. To increase the validity of this evaluation, data will be collected from multiple sources and compared for similarities and/or differences (triangulation).

Qualitative methods lie at the core of this implementation evaluation. They provide an understanding beyond numbers of *how* the program achieves its level of impact. *Open-ended interviews* with program participants and members of program staff will provide data to assess how the components of the Family Action Plan (FAP) function and interact to create improved outcomes for program participants. These interviews must be open-ended to capture different perspectives without predetermining them through selection of questionnaire categories (Patton, 2002). They will also provide insight into what the local personnel identify as strengths or weaknesses of the different program components.

Document review refers to reviewing program-related material. These documents may range from activity logs (i.e. visits with particular services within the program), program literature written for public distribution, and Nutrition, Psychology, or Social Work reports of or for participants. Document review may also include each participant's log of visits as maintained by the Attendance Team Coordinator.

The following quantitative methods will be used to provide objective measurements alongside qualitative data: reviewing numerical trends of pediatric hospitalizations of program participants from the affiliated hospital health records or database.

3.Will this study use any of the following methods?

- ✗ Audiotaping
- ✗ Videotaping or filming
- ✗ Behavioral observation - (e.g., Participant, naturalistic, experimental, and other observational methods typically used in social science research)
- ✗ Pencil and paper questionnaires or surveys
- ✗ Electronic questionnaires or surveys
- ✗ Telephone questionnaires or surveys
- ✓ Interview questionnaires or surveys
- ✗ Other questionnaires or surveys
- ✗ Focus groups
- ✗ Diaries or journals
- ✗ Photovoice
- ✗ Still photography

4.If there are procedures or methods that require specialized training, describe who (role/qualifications) will be involved and how they will be trained.

No Answer Provided

5.Are there cultural issues, concerns or implications for the methods to be used with this study population?

No

A.6. Risks and measures to minimize risks

For each of the following categories of risk you will be asked to describe any items checked and what will be done to minimize the risks. Where possible, describe the likelihood of the risks occurring, using the following terms:

- ***Very Common*** *(approximate incidence > 50%)*
- ***Common*** *(approximate incidence > 25%)*
- ***Likely*** *(approximate incidence of 10-25%)*
- ***Infrequent*** *(approximate incidence of 1-10%)*
- ***Rare*** *(approximate incidence < 1%)*

1.Psychological

- ✘ Emotional distress
- ✘ Embarrassment
- ✘ Consequences of breach of confidentiality
- ✘ Other

Describe any items checked above and what will be done to minimize these risks

No Answer Provided

2.Social

- ✘ Loss of reputation or standing within the community
- ✘ Harms to a larger group or community beyond the subjects of the study (e.g., stigmatization)
- ✘ Consequences of breach of confidentiality
- ✘ Other

Describe any items checked above and what will be done to minimize these risks

No Answer Provided

3.Economic

- ✘ Loss of income
- ✘ Loss of employment or insurability
- ✘ Loss of professional standing or reputation
- ✘ Loss of standing within the community
- ✘ Consequences of breach of confidentiality
- ✘ Other

Describe any items checked above and what will be done to minimize these risks

No Answer Provided

4.Legal

- ✘ Disclosure of illegal activity

- ✖ Disclosure of negligence
- ✖ Consequences of breach of confidentiality
- ✖ Other

Describe any items checked above and what will be done to minimize these risks

No Answer Provided

5.Physical

- ✖ Medication side effects
- ✖ Pain
- ✖ Discomfort
- ✖ Injury
- ✖ To a nursing child or a fetus (either through mother or father)

Describe any items checked above, including the category of likelihood and what will be done to minimize these risks

No Answer Provided

6.Unless already addressed above, describe procedures for referring subjects who are found, during the course of this study, to be in need of medical follow-up or psychological counseling

No Answer Provided

7.Are there plans to follow subjects or partners of subjects who become pregnant while enrolled in this study?

No

A.9. Identifiers

1.Check all of the following identifiers you will be receiving. This does not apply to information on consent forms.

- ✖ Names
- ✖ Telephone numbers
- ✖ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- ✖ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
- ✖ Fax numbers
- ✖ Electronic mail addresses
- ✖ Social security numbers
- ✖ Medical record numbers
- ✖ Health plan beneficiary numbers
- ✖ Account numbers

- ✗ Certificate/license numbers
- ✗ Vehicle identifiers and serial numbers (VIN), including license plate numbers
- ✗ Device identifiers and serial numbers (e.g., implanted medical device)
- ✗ Web universal resource locators (URLs)
- ✗ Internet protocol (IP) address numbers
- ✗ Biometric identifiers, including finger and voice prints
- ✗ Full face photographic images and any comparable images
- ✗ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

2.For any identifiers checked, how will these identifiers be stored in relationship to the research data?

- ✗ with the research data (i.e., in the same data set and/or physical location)
- ✗ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

3.Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

A.10. Confidentiality of the data

1.Describe procedures for maintaining confidentiality of the data you will collect or will receive (e.g., coding, anonymous responses, use of pseudonyms, etc.).

All voluntary participants will be assigned a numerical representation so that no identifying information will be connected to the individual.

2.Will any of the groupings or subgroupings used in analysis be small enough to allow individuals to be identified?

No

Part B. Direct Interaction

B.1. Methods of recruiting

1.Check all the following means/methods of subject recruitment to be used:*

- ✓ In person
- ✗ Participant pools
- ✗ Presentation to classes or other groups
- ✗ Letters
- ✗ Flyers
- ✗ Radio, TV recruitment ads
- ✗ Newspaper recruitment ads

- ✗ Website recruitment ads
- ✗ Telephone script
- ✗ Email or listserv announcements
- ✗ Other

2.Describe how subjects will be identified

Subjects of this study include NGO staff, participants, and stakeholders. They will be identified on site in Rio de Janeiro under the guidance and supervision of the HR director of the NGO.

3.Describe how and where subjects will be recruited and address the likelihood that you will have access to the projected number of subjects identified in A.2.

Subjects will be recruited on site in Rio de Janeiro at the NGO. The PI will describe the purpose of the study and gain consent, after which the PI will conduct an interview. Any and all participation is voluntary.

Attachments

File Name	Document Type
✓ Tinker Fellowship Application_Doshi.docx Required	Grant Application
✓ IRB Interview Guide.docx Required	Interview Questionnaire Survey

view attachments

Addenda

Data Security Requirements

view addenda

By certifying below, the Principal Investigator affirms the following:

I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

This study proposes research that has been determined to include Security Level 1 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If PI is a Student or Trainee Investigator, the Faculty Advisor also certifies the following:

I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

Certifying Signatures:

Signature:	Electronic Signature Received	**Date:**	3/18/2012 11:06:19 PM
	Neeti Doshi		
Signature:	Electronic Signature Received	**Date:**	3/19/2012 09:03:14 AM
	Diane Calleson		

The expectation is that this approval is being given on behalf of the head of the Department, Division, or Center. If the chair or director is an investigator on this project or otherwise conflicted in approving it, the Vice-Chair or Chair's designee should review it. By approving, you are certifying the following on behalf of your department, division or center:

- This research is appropriate for this Investigator and our department
- The investigator(s) are qualified to conduct the research
- There are adequate resources (including financial, support and facilities) available
- For units that have a local review committee for pre-IRB review, this requirement has been satisfied
- I support this application, and hereby submit it for further review

This study proposes research that has been determined to include Security Level 1 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If you are approving for other purposes (e.g., CTRC, DSMB, IBC, PRC, RSC, or other review committees), you affirm the following:

- The proposed submission is approved and may be forwarded for IRB review.

This study proposes research that has been determined to include Security Level 1 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

Department Approval Signatures:

By signing in the appropriate space, the Department Chairperson(s) is indicating only that he/she has seen and reviewed this submission

Department:	Public Health Leadership Program		
Signature:	Electronic Signature Received	**Date:**	3/25/2012 10:36:41 AM
Name & Title:	Anna Schenck, Professor of the Practice		